UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant ☑

Filed by a Party other than the Registrant o

Check the appropriate box:

- o Preliminary Proxy Statement
- o Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
- ☒ Definitive Proxy Statement
- o Definitive Additional Materials
- o Soliciting Material Pursuant to §240.14a-12

NewLink Genetics Corporation

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement if Other Than the Registrant)

Payment of Filing Fee (Check the appropriate box)

- o No fee required.
- o Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

1. Title of each class of securities to which transaction applies:
   Common Stock of NewLink Genetics Corporation, par value $0.01 per share
2. Aggregate number of securities to which transaction applies:
   39,184,506 shares of common stock of NewLink Genetics Corporation ("NewLink") to be issued or issuable pursuant to that certain Agreement and Plan of Merger and Reorganization, dated as of September 30, 2019, by and among NewLink, Cyclone Merger Sub, Inc., a wholly-owned subsidiary of NewLink, and Lumos Pharma, Inc. ("Lumos"), assuming the exchange ratios determined based on information as to equity ownership as of December 31, 2019 and other assumptions discussed in this proxy statement, including the assumption that former Lumos stockholders will own approximately 50% of the combined company's common stock and that NewLink stockholders will own approximately 50% of the combined company's common stock.
3. Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (Set forth the amount on which the filing fee is calculated and state how it was determined):
   The maximum aggregate value was determined based upon 39,184,506 shares of NewLink's common stock to be issued or issuable in the transaction to Lumos stockholders, multiplied by $1.62, which is the average of the high and low trading prices as reported on The Nasdaq Global Market within five business days prior to February 4, 2020. The filing fee was determined by multiplying $0.0001298 by the maximum aggregate value of the transaction as determined in accordance with the preceding sentence.
4. Proposed maximum aggregate value of transaction:
   $63,478,899.72
5. Total fee paid:
   $8,239.56*

* Includes $7,773.96 previously paid on November 20, 2019 on Schedule 14A Preliminary Proxy Statement and $3,059.54 previously paid on January 9, 2020 on Schedule 14A Preliminary Proxy Statement.

- ☑ Fee paid previously with preliminary materials.
- o Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

6. Amount Previously Paid:
7. Form, Schedule or Registration Statement No.:
8. Filing Party:
9. Date Filed:

NEWLINK GENETICS CORPORATION
2503 South Loop Drive
Ames, IA 50010

NOTICE OF SPECIAL MEETING OF STOCKHOLDERS
TO BE HELD ON MARCH 17, 2020

Dear Stockholder:

You are cordially invited to attend the Special Meeting of Stockholders (the "Special Meeting") of **NEWLINK GENETICS CORPORATION**, a Delaware corporation ("NewLink" or the "Company"). The Special Meeting will be held on March 17, 2020 at 9:00 a.m. local time at ISU Economic Development Core Facility, 1805 Collaboration Place, Ames, IA 50010.

As previously announced, on September 30, 2019, NewLink, Cyclone Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company ("Merger Sub"), and Lumos Pharma, Inc., a privately-held Delaware corporation ("Lumos"), entered into an Agreement and Plan of Merger and Reorganization (as amended, the "Merger Agreement"), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Lumos, with Lumos surviving as a wholly-owned subsidiary of NewLink (the "Merger"). Following the Merger, NewLink will change its name to "Lumos Pharma, Inc." (the "combined company") and Lumos will change to a name mutually agreed upon by the Company and Lumos.

Subject to the terms and conditions of the Merger Agreement, at the Effective Time (as defined therein and in the accompanying proxy statement) of the Merger, each share of Lumos capital stock outstanding immediately prior to the Effective Time (excluding shares of Lumos capital stock held as treasury stock or held or owned by Lumos or Merger Sub prior to the Effective Time and shares held by Lumos stockholders who have exercised and perfected appraisal rights in accordance with Delaware law) shall be automatically converted solely into the right to receive a number of shares of NewLink's common stock equal to the amount determined pursuant to a charter amendment to Lumos' certificate of incorporation that will be filed prior to the Effective Time, at exchange ratios applicable to each type of Lumos capital stock as set forth therein and in the accompanying proxy statement. Pursuant to such conversion, immediately following the Merger, former Lumos stockholders will own approximately 50% of the aggregate number of shares of Company common stock issued and outstanding following the effective time of the Merger (the "Post-Closing Shares"), and the stockholders of the Company as of immediately prior to the Merger will own approximately 50% of the aggregate number of Post-Closing Shares. Outstanding options to purchase Lumos common stock will be assumed by NewLink and converted into options to purchase a number of shares of NewLink's common stock at the exchange ratio applicable to exchanging shares of Lumos common stock for NewLink's common stock.

NewLink is holding the Special Meeting in order to obtain the stockholder approvals necessary to complete the Merger. Pursuant to rules of The Nasdaq Stock Market LLC ("Nasdaq"), the issuance of NewLink's common stock requires NewLink stockholders' approval because it exceeds 20% of the number of shares of NewLink's common stock outstanding prior to the issuance and does not constitute a "public offering" as defined under Nasdaq's rules. Furthermore, the issuance of the shares requires NewLink stockholders' approval under Nasdaq's rules because it will result in a "change of control" of NewLink. The Special Meeting will be held for the purposes listed below:

1. To approve the issuance of NewLink's common stock pursuant to the Merger Agreement, as well as the resulting "change of control" of NewLink under Nasdaq rules (the "Merger Proposal");
2. To amend NewLink's amended and restated certificate of incorporation to effect a reverse stock split of NewLink's common stock (the "Reverse Stock Split Proposal");
3. To approve, on a non-binding advisory basis, certain compensation that may be paid or become payable to certain of NewLink's named executive officers in connection with the Merger (the "Compensation Proposal");

4. To adjourn or postpone the Special Meeting, if necessary or appropriate, for the purpose of soliciting additional votes for the approval of the Merger Proposal or the Reverse Stock Split Proposal (the "Adjournment Proposal"); and

5. To conduct any other business properly brought before the meeting.

These items of business are more fully described in the accompanying proxy statement.

After careful consideration, NewLink's board of directors (the "NewLink Board") has unanimously determined that the Merger Agreement and the transactions contemplated thereby, including the Merger, are advisable, fair to and in the best interests of NewLink and its stockholders and recommends that you vote "FOR" the Merger Proposal (Proposal 1); "FOR" the Reverse Stock Split Proposal (Proposal 2); "FOR" the Compensation Proposal (Proposal 3); and "FOR" the Adjournment Proposal (Proposal 4) if necessary to solicit additional proxies if there are not sufficient votes to approve the Merger Proposal or the Reverse Stock Split Proposal.

The record date for the Special Meeting is February 7, 2020. Only stockholders of record at the close of business on that date may vote at the Special Meeting or any adjournment thereof. All NewLink stockholders are invited to attend the Special Meeting in person. Whether or not you expect to attend the Special Meeting, please vote your shares as promptly as possible using the enclosed proxy card, or via the internet or telephone as instructed in the enclosed materials, in order to ensure your representation at the Special Meeting. We encourage you to read the accompanying proxy statement and the Merger Agreement and other annexes to the proxy statement carefully and in their entirety. **In particular, you should carefully consider the matters discussed under "Risk Factors" beginning on page 17.**

Your vote is very important, regardless of the number of shares of our voting securities that you own. I encourage you to vote by telephone, over the internet, or by marking, signing, dating and returning your proxy card so that your shares will be represented and voted at the Special Meeting, whether or not you plan to attend. If you attend the Special Meeting, you will, of course, have the right to revoke the proxy and vote your shares in person.

On behalf of the NewLink Board, I urge you to submit your proxy as soon as possible, even if you currently plan to attend the Special Meeting in person.

Thank you for your support of NewLink. I look forward to seeing you at the Special Meeting.

Sincerely,

On behalf of the NewLink Board

/s/ Carl W. Langren
Carl W. Langren
Chief Financial Officer

Ames, Iowa
February 10, 2020

Neither the Securities and Exchange Commission nor any state securities regulatory agency has approved or disapproved of the Merger described in this proxy statement or NewLink's common stock to be issued in connection with the Merger or determined if this proxy statement is accurate or adequate. Any representation to the contrary is a criminal offence.

Important Notice Regarding the Availability of Proxy Materials for the NewLink Special Meeting to be Held on March 17, 2020:

Our official Notice of Special Meeting of Stockholders and proxy statement are available at www.proxyvote.com.

You are cordially invited to attend the Special Meeting in person. Whether or not you expect to attend the Special Meeting, please complete, date, sign and return the enclosed proxy card, or vote over the telephone or the internet, so that your shares may be voted in accordance with your wishes and in order that the presence

of a quorum may be assured. Even if you have voted by proxy, you may still vote in person if you attend the Special Meeting. Please note, however, that if your shares are held of record by a broker, bank or other agent and you wish to vote at the Special Meeting, you must obtain a proxy issued in your name from that record holder. Your vote is important.

You may vote by proxy by completing and mailing the enclosed proxy card. If you submit a proxy card, we will vote your shares as you direct. If you submit a proxy card without giving specific voting instructions for a particular proposal, those shares will be voted as recommended by the NewLink Board with respect to such proposal.

If you have a NewLink stock certificate or hold your shares in an account with our transfer agent, Computershare, you may also vote by proxy via the internet by going to the website www.proxyvote.com, and following the instructions provided there, or by telephone, by calling the following number: 1-800-690-6903 using a touch-tone phone and follow the recorded instructions. Have your proxy card in hand when you call and then follow the instructions. Your proxy card, internet or telephone vote must be received by 11:59 p.m., Eastern Time, on March 16, 2020, to be counted.

We intend to provide definitive copies of our proxy materials to our stockholders on or about February 10, 2020. We will make all of our proxy materials available on the internet at www.proxyvote.com, beginning on or about February 10, 2020.

If your shares are held by a broker, bank or other agent, you are considered the beneficial owner of those shares, and your shares are held in “street name.” If you hold your shares in “street name” you will receive instructions from your broker, bank or other agent describing how to vote your shares. If you hold shares in “street name” and do not receive instructions on how to vote your shares, you should contact your broker, bank or other agent promptly and request this information.

Even if you have voted by proxy via one of the procedures listed above, you may still vote in person if you attend the Special Meeting. Please note, however, that if your shares are held of record by a broker, bank or other agent and you wish to vote at the Special Meeting, you must obtain a proxy issued in your name from that record holder.

NEWLINK GENETICS CORPORATION

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NEWLINK GENETICS CORPORATION
2503 South Loop Drive
Ames, Iowa 50010

PROXY STATEMENT
FOR THE SPECIAL MEETING OF STOCKHOLDERS

TO BE HELD ON MARCH 17, 2020

To the Stockholders of NewLink Genetics Corporation:

A Special Meeting of Stockholders (the "Special Meeting") of NewLink Genetics Corporation ("NewLink" or the "Company") will be held at 9:00 a.m. local time, on March 17, 2020, at ISU Economic Development Core Facility, 1805 Collaboration Place, Ames, IA 50010, to consider and act upon the following matters:

1. To approve the issuance of NewLink's common stock pursuant to an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") entered into by and among NewLink, Cyclone Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company ("Merger Sub"), and Lumos Pharma, Inc., a privately-held Delaware corporation ("Lumos"), as well as the resulting "change of control" of NewLink under Nasdaq Stock Market rules (the "Merger Proposal");
2. To amend NewLink's amended and restated certificate of incorporation to effect a reverse stock split of NewLink's common stock (the "Reverse Stock Split Proposal");
3. To approve, on a non-binding advisory basis, certain compensation that may be paid or become payable to certain of NewLink's named executive officers in connection with the merger (the "Merger") contemplated by the Merger Agreement (the "Compensation Proposal");
4. To adjourn or postpone the Special Meeting, if necessary or appropriate, for the purpose of soliciting additional votes for the approval of the Merger Proposal or the Reverse Stock Split Proposal (the "Adjournment Proposal"); and
5. To conduct any other business properly brought before the meeting.

These items of business are more fully described in the accompanying proxy statement.

NewLink stockholders also will consider and act on any other matters as may properly come before the Special Meeting or any adjournment or postponement thereof, including any procedural matters incident to the conduct of the Special Meeting.

NewLink's common stock is the only type of security entitled to vote at the Special Meeting. The NewLink board of directors (the "NewLink Board") has fixed February 7, 2020 as the record date for the determination of stockholders entitled to notice of, and to vote at, the Special Meeting and any adjournment or postponement thereof. Only holders of record of shares of NewLink's common stock at the close of business on the record date are entitled to notice of, and to vote at, the Special Meeting. At the close of business on the record date, 37,328,425 shares of NewLink's common stock were issued and outstanding and entitled to vote at the Special Meeting. Each holder of record of shares of NewLink's common stock on the record date will be entitled to one vote for each share held on all matters to be voted upon at the Special Meeting.

Your vote is important. The affirmative vote of the majority of votes cast affirmatively or negatively is required for approval of Proposals 1, 3 and 4 (Merger Proposal, Compensation Proposal and Adjournment Proposal). The affirmative vote of holders of a majority of the outstanding shares of NewLink's common stock entitled to vote at the Special Meeting is required for approval of Proposal 2 (Reverse Stock Split Proposal).

Whether or not you plan to attend the Special Meeting in person, please submit your proxy promptly by telephone or via the internet in accordance with the instructions on the enclosed proxy card or complete, date, sign and promptly return the accompanying proxy card in the enclosed postage paid envelope to ensure that your shares will be represented and voted at the Special Meeting. If you date, sign and return your proxy card without indicating how you wish to vote, your proxy will be counted as a vote in favor of Proposals 1 through 4. If you fail either to return your proxy card or to vote in person at the Special Meeting, your shares will not be counted for purposes of determining whether a quorum is present at the Special Meeting and will have the same effect as a vote against Proposal 2 (Reverse Stock Split Proposal), but assuming a quorum is present at the Special Meeting, will have no

effect on the outcome of Proposal 1, 3 or 4 (Merger Proposal, Compensation Proposal or Adjournment Proposal). If you attend the Special Meeting, you may, upon your written request, withdraw your proxy and vote in person. You may revoke your proxy at any time before the polls close at the Special Meeting by sending a written notice to our Secretary at 2503 South Loop Drive, Suite 5100, Ames, IA 50010, by providing a duly executed proxy card bearing a later date than the proxy being revoked, by submitting a proxy on a later date by telephone or via the internet (only your last telephone or internet proxy will be counted) before 11:59 p.m. Eastern Time on March 16, 2020 or by attending the Special Meeting and voting in person.

SUMMARY

This summary highlights information contained elsewhere in this proxy statement and may not contain all the information that is important to you with respect to the Merger, Merger Agreement, the issuance of NewLink's common stock pursuant to the Merger Agreement and the resulting "change of control" of NewLink under Nasdaq rules and the other matters being considered at the Special Meeting of Stockholders (the "Special Meeting") to which this proxy statement relates. We urge you to read carefully the remainder of this proxy statement, including the attached annexes, and the other documents to which we have referred you. For additional information on NewLink, see "Where You Can Find More Information" beginning on page 166. We have included page references in this summary to direct you to a more complete description of the topics presented below.

All references in this proxy statement to:

- "NewLink," the "Company," "we," "us," or "our" refer to NewLink Genetics Corporation,
- "Lumos" refer to Lumos Pharma, Inc.,
- "Effective Time" refer to the effective time of the Merger,
- "Merger" refer to the merger subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, whereby Merger Sub will merge with and into Lumos, with Lumos surviving as a wholly-owned subsidiary of NewLink,
- "Merger Sub" refer to Cyclone Merger Sub, Inc.,
- the "Merger Agreement" refer to the Agreement and Plan of Merger and Reorganization, dated as of September 30, 2019, by and among NewLink, Merger Sub and Lumos, as amended on November 19, 2019,
- "Nasdaq" refer to The Nasdaq Global Market or The Nasdaq Stock Market LLC, as applicable, and
- the "combined company" refer to NewLink, to be renamed as Lumos Pharma, Inc., as the combined company immediately following the Effective Time.

The Companies

NewLink Genetics Corporation
2503 South Loop Drive
Ames, Iowa 50010
(515) 296-5555

NewLink is a Delaware corporation founded in 1999. Our principal executive office is located in Ames, Iowa, with an additional office located in Wayne, Pennsylvania. We are a clinical-stage immuno-oncology company that has historically focused on developing novel immunotherapeutic products for the treatment of patients with cancer. Our leading small-molecule product candidates currently in clinical development target the indoleamine-2, 3-dioxygenase ("IDO") pathway, which is one of the key pathways for cancer immune escape. These product candidates, indoximod and NLG802 (a prodrug of indoximod), are IDO pathway inhibitors with mechanisms of action that center around breaking the immune system's tolerance to cancer. We also have an additional small molecule product candidate, NLG207, which is a nanoparticle-drug conjugate consisting of a cyclodextrin-based polymer backbone linked to camptothecin, a topoisomerase 1 inhibitor, which has been out-licensed to Ellipses Pharma Limited, effective December 17, 2019.

After the consummation of the Merger, the combined company expects to focus its efforts on the development of Lumos' sole product candidate, LUM-201 (ibutamoren), a potential oral therapy for pediatric growth hormone deficiency ("PGHD") and other rare endocrine disorders. Our management does not intend to pursue further internal development of our existing pipeline upon consummation of the Merger, but will continue to evaluate our pipeline pending results of the diffuse intrinsic pontine glioma ("DIPG") cohort of our Phase 1b clinical trial for indoximod and, depending on such results, may seek to identify potential partnerships and licensing opportunities.

In November 2014, we entered into an exclusive, worldwide license and collaboration agreement (the "Merck Agreement"), with Merck Sharp and Dohme Corp. ("Merck") to develop and potentially commercialize our Ebola vaccine V920 product candidate and other aspects of our vaccine technology. The Ebola vaccine V920 product candidate was originally developed by the Public Health Agency of Canada and is designed to utilize the rVSV vector

to induce immunity against the Ebola virus when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. Merck announced in September 2019 that the FDA had accepted its biologics license application ("BLA") filing and granted priority review for the Ebola vaccine V920.

On December 20, 2019, Merck announced that the U.S. Food and Drug Administration (the "FDA") has approved its application for ERVEBO® (Ebola Zaire Vaccine, Live) for the prevention of disease caused by Zaire ebolavirus in individuals 18 years of age and older. As a result, Merck is eligible to receive a priority review voucher ("PRV"). On January 3, 2020, Merck notified NewLink that a PRV has been issued to Merck. Under the terms of the Merck Agreement, upon NewLink's written request, Merck will transfer all of its rights and interests in connection with the PRV to NewLink, and NewLink is entitled to 60% of the value of the PRV obtained through sale, transfer or other disposition of the PRV. Our common stock is traded on The Nasdaq Global Market under the symbol "NLNK."

Cyclone Merger Sub, Inc.
2503 South Loop Drive
Ames, Iowa 50010
(515) 296-5555

Merger Sub is a wholly-owned subsidiary of NewLink that was recently incorporated in Delaware for the purpose of the Merger. It does not conduct any business and has no material assets.

Lumos Pharma, Inc.
4200 Marathon Blvd., Suite 200
Austin, Texas 78756
(512) 215-2630

Lumos is a Delaware corporation founded in 2011. Its principal executive office is located in Austin, Texas. Lumos is a biopharmaceutical company focused on the identification, acquisition, in-license, development, and commercialization of novel products for the treatment of rare diseases. Lumos' current pipeline is focused on the future development of an orally administered small molecule, the growth hormone ("GH") secretagogue ibutamoren ("LUM-201," previously MK-0677 and L-163,191) for three rare endocrine disorders. A secretagogue is a substance that stimulates the secretion or release of another substance. LUM-201 stimulates the release of GH and is referred to as a GH secretagogue. The current targeted indications for LUM-201 are PGHD, Turner Syndrome and Children Born Small for Gestational Age ("SGA"), in each case in a certain subset of affected patients. Lumos intends to file an Investigational New Drug ("IND") application with the FDA with respect to its planned PGHD Phase 2b clinical trial in the first quarter of 2020. Prior development of LUM-201, then known as MK-0677, was conducted by Merck, including two Phase 2 clinical trials in PGHD patients in 1996 and 1997. Although such trials were ended early due to lack of efficacy, further analysis by Lumos suggests that higher doses and limiting the participants in the planned LUM-201 Phase 2b clinical trial to a certain subset of PGHD patients that meet pre-defined Predictive Enrichment Markers ("PEMs") has the potential to enable Lumos to select the dose and cohort size for a Phase 3 trial to show noninferiority. Merck had manufactured multiple lots of the active ingredient of LUM-201 in 2005 that Lumos plans to use in the upcoming Phase 2b clinical trial, if allowed by the FDA upon the IND filing. Lumos believes such material meets all necessary FDA requirements for use, but if not allowed by the FDA, new material would be manufactured for use in the Phase 2b clinical trial and the trial start date would be delayed by approximately one year. Certain source documentation from the clinical trials completed by Merck is unavailable. Lumos believes such missing documentation will not impact future development of LUM 201. However, the lack of such documentation may be a factor that impacts the LUM-201 clinical development timeline. The composition of matter patent for LUM-201 has expired and Lumos does not have composition of matter protection in the United States or elsewhere covering LUM-201. Since Lumos does not have a composition of matter patent on LUM-201 and the chemical structure of LUM-201 is in the public domain, it is possible for another company to develop LUM-201 for another indication and market the drug for indications where Lumos does not have granted methods of treatment claims or, if approved by the FDA and EMA for its orphan-designated indications, market exclusivity. If LUM-201 is approved, Lumos may be limited in its ability to list its patents in the FDA's Orange Book if the use of its product, consistent with its FDA-approved label, would not fall within the scope of Lumos' patent claims. Also, Lumos' competitors may be able to offer and sell products so long as these competitors do not infringe any other patents that Lumos (or third parties) hold, including patents with claims for method of use patents. FDA approval of uses that are not covered by Lumos' patents would limit Lumos' ability to generate revenue from the sale of LUM-201, if approved for commercial sale. See "Risk Factors — Risks Related to Lumos' Intellectual Property — Lumos does not have

composition of matter patent protection with respect to LUM-201" for more information. Lumos has been granted a U.S. method of use patent (and similar applications pending in other regions) directed at growth hormone deficiency disorders. If approved, LUM-201 has the potential to become the first approved oral GH secretagogue to treat rare endocrine disorders associated with GH deficiencies, starting with PGHD, providing an alternative to the current standard regimen of daily injections.

The Combined Company

Immediately following the Effective Time, the pre-Merger NewLink stockholders and the pre-Merger Lumos stockholders will each own approximately 50% of the outstanding common stock of the combined company as discussed in "The Merger Agreement — Exchange Ratios." The principal executive office of the combined company is expected to be located in Austin, Texas.

Summary of the Merger

Upon the terms and subject to the conditions of the Merger Agreement, Merger Sub, a wholly-owned subsidiary of NewLink formed by NewLink in connection with the Merger, will merge with and into Lumos. The Merger Agreement provides that at the Effective Time the separate existence of Merger Sub shall cease. Lumos will continue as the surviving corporation and will be a wholly-owned subsidiary of NewLink. Immediately following the Effective Time, NewLink stockholders will own approximately 50% of the outstanding common stock of the combined company and Lumos stockholders will own approximately 50% of the outstanding common stock of the combined company. Following the Merger, NewLink will change its name to "Lumos Pharma, Inc." and Lumos will change its name to a name that is mutually agreed upon by NewLink and Lumos.

Consummation of the Merger is subject to the satisfaction or waiver of a number of conditions (subject to certain exceptions in the Merger Agreement), including, among others, NewLink stockholders' approval of the Merger Proposal and the Reverse Stock Split Proposal for the purpose of maintaining compliance with Nasdaq listing standards.

NewLink's Reasons for the Merger (see page 66)

The primary reason that NewLink's board of directors (the "NewLink Board") approved the Merger is to create a combined company that will be a clinical-stage biopharmaceutical company focused on developing novel treatments for rare diseases. The NewLink Board believes that the combined company will offer the following potential advantages to NewLink stockholders:

- *Clinical-Stage Specialty Biopharmaceutical Company.* The combined company will be focused on advancing further Lumos' sole product candidate, LUM-201, to potentially be, if approved, the first oral treatment for a subset of PGHD patients and developing novel treatments for other rare diseases.
- *Management Team.* The combined company will be led by experienced senior management from both NewLink and Lumos and a board of directors of seven members with three designated by NewLink, three designated by Lumos, and one to be designated following the Merger by the board of directors of the combined company.
- *Cash Resources.* The combined company is expected to be sufficiently funded to enable the combined company to implement its near-term business plans, including the Phase 2b clinical trial for LUM-201.
- *Cost Savings*. The combined company may be able to achieve cost savings and synergies from, among other things, reductions in corporate overhead and administrative costs in comparison to both companies on a stand-alone basis.

In approving the Merger, the NewLink Board considered a number of factors, including the following:

- the strategic alternatives of NewLink to the Merger, including potential transactions that could have resulted from discussions that NewLink management conducted with other potential strategic partners and the belief that the Merger with Lumos would provide NewLink stockholders with a greater potential opportunity to realize a return on their investment than any other alternative reasonably available to NewLink stockholders at that time;
- the opportunity for NewLink stockholders to participate in the potential increase in value that may result from the development of Lumos' product candidate and of the combined company following the Merger;

- the risks of continuing to operate NewLink on a stand-alone basis given current market sentiment toward IDO inhibitors as a class and the likelihood that market conditions for NewLink would not change for the benefit of NewLink stockholders in the foreseeable future on a stand-alone basis; and
- Stifel, Nicolaus & Company, Incorporated's ("Stifel") opinion to the NewLink Board that the merger consideration to be paid by NewLink (the "Merger Consideration") in the Merger pursuant to the Merger Agreement was fair, from a financial point of view, to NewLink, as more fully described below under the caption "Opinion of NewLink's Financial Advisor."

Lumos' Reasons for the Merger (see page 84)

The primary reason that the board of directors of Lumos (the "Lumos Board") approved the Merger is to create a combined company that will be a clinical-stage biopharmaceutical company focused on developing novel treatments for rare diseases. The Lumos Board believes that the combined company will offer the following potential advantages to Lumos stockholders:

- *Clinical-Stage Specialty Biopharmaceutical Company.* Lumos will be focused on developing novel treatments for rare diseases and continuing to advance its sole product candidate, LUM-201, to potentially be, if approved, the first oral treatment for a subset of PGHD patients.
- *Management Team.* It is expected that the combined company will be led by the experienced Chief Executive Officer from Lumos, with key executives from both NewLink and Lumos and a board of directors with representation from each of Lumos and NewLink.
- *Cash Resources.* The combined company is expected to have, on a pro forma basis, approximately $80 million in cash and cash equivalents at December 31, 2019, after providing for restructuring and severance costs and reserves, transaction costs and potential employee bonuses which may not be fully paid out as of December 31, 2019. The Lumos Board believes such cash resources will be sufficient to enable the combined company to implement its near-term business plans. Additional cash may be obtained upon the issuance and monetization of the PRV to NewLink's licensee, Merck, if Merck's BLA for the licensed Ebola vaccine is approved by the FDA. On December 20, 2019, Merck announced that the FDA had approved its application for ERVEBO® (Ebola Zaire Vaccine, Live) for the prevention of disease caused by Zaire ebolavirus in individuals 18 years of age and older. On January 3, 2020, Merck notified NewLink that a PRV had been issued to Merck.

In approving the Merger, the Lumos Board considered a number of factors, including the following:

- the process undertaken by the Lumos Board and management to ascertain alternatives to the Merger, including partnering transactions and private fundraising transactions;
- the possible alternatives to the Merger, the range of possible benefits to the Lumos stockholders of such alternatives and the timing and the likelihood of completing and accomplishing the goal of any of such alternatives;
- the financial condition, historical results of operations and business and strategic objectives of Lumos, as well as the risks involved in achieving those objectives;
- the amount and form of consideration to be received by the Lumos stockholders in the Merger pursuant to the Merger Agreement taking into account whether any alternatives to the Merger would reasonably likely be achievable and derive more value for the Lumos stockholders;
- the expectation that the Merger will be treated as a tax-deferred reorganization for United States federal income tax purposes; and
- the expected duration of the interim period between the signing of the Merger Agreement and the expected closing and whether it is advisable to proceed given current economic, industry and market conditions.

Opinion of NewLink's Financial Advisor (see page 72 and Annex F)

At a meeting of the NewLink Board on September 30, 2019, Stifel rendered its oral opinion, subsequently confirmed in writing by delivery of a written opinion, to the NewLink Board that, as of that date and based upon and subject to the factors, limitations and assumptions set forth in its opinion, the Merger Consideration to be paid by NewLink in the Merger pursuant to the Merger Agreement was fair to NewLink from a financial point of view.

The full text of the written opinion of Stifel, dated September 30, 2019, which sets forth, among other things, the assumptions made, procedures followed, matters considered and qualifications and limitations on the opinion and review undertaken in connection with rendering its opinion, is included as Annex F to this proxy statement and is incorporated herein by reference. Stifel's opinion is addressed to the NewLink Board, is directed only to the consideration of the financial terms of the Merger and does not constitute a recommendation to the NewLink Board as to how the NewLink Board should vote on the Merger or any stockholder of NewLink as to how such stockholder should vote with respect to the Merger or any other matter, including whether or not any NewLink or Lumos stockholder should exercise any dissenters', appraisal or similar rights that may be available to such stockholder. The summary of Stifel's opinion set forth in this proxy statement is qualified in its entirety by reference to the full text of such opinion. For additional information relating to Stifel's opinion, see "The Merger — Opinion of NewLink's Financial Advisor" beginning on page 72.

The Board of Directors Following the Merger (see page 145)

At the Effective Time, the board of directors of the combined company will consist of three members designated by NewLink, and three members designated by Lumos. One member is to be designated following the Merger by the board of directors of the combined company.

Interests of NewLink's Directors and Executive Officers in the Merger (see page 68)

NewLink's directors and executive officers have economic interests in the Merger that are different from, or in addition to, those of NewLink stockholders generally. These interests include:

- NewLink's executive officers are parties to employment agreements that provide for severance and change in control benefits in the event of certain qualifying terminations of employment in certain circumstances, including following the Merger;
- with respect to NewLink's executive officers, the vesting of their outstanding equity awards granted under NewLink's 2009 Equity Incentive Plan (as amended, the "2009 Plan") will be accelerated by 12 months upon closing of the Merger;
- with respect to NewLink's directors who will resign in connection with the Merger, the vesting of their outstanding equity awards granted under the 2009 Plan will be 100% accelerated upon closing of the Merger and the exercise period for such awards will be extended until the one-year anniversary of their respective resignations; and
- Certain NewLink directors and executive officers will provide continued service as directors or executive officers of the combined company.

These interests are discussed in more detail in "The Merger — Interests of NewLink's Directors and Executive Officers in the Merger." The NewLink Board was aware of and considered these interests, among other matters, in reaching its decision to approve and declare advisable the Merger Agreement, the Merger and the other transactions contemplated by the Merger Agreement.

Federal Securities Law Consequences; Resale Restrictions (see page 87)

The issuance of NewLink's common stock in the Merger to Lumos stockholders will be effected by means of a private placement, which is exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance on Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder and such shares will be "restricted securities." The shares issued in connection with the Merger will not be registered under the Securities Act upon issuance and will not be freely transferable. Holders of such shares may not sell their respective shares unless the shares are registered under the Securities Act or an exemption is available under the Securities Act.

The Merger Agreement provides that NewLink will, within 90 days after the closing of the Merger, file a registration statement on Form S-3 (or other appropriate form) to register all such shares for resale, and to use commercially reasonable efforts to cause such registration statement to be effective for three years so long as the shares of NewLink's common stock issued in the Merger remain outstanding without a transfer exemption under the Securities Act. See also "The Merger Agreement — Merger Consideration."

Material U.S. Federal Income Tax Consequences of the Reverse Stock Split and the Merger (see page 87)

The reverse stock split is expected to constitute a "recapitalization" for U.S. federal income tax purposes. As a result, a U.S. Holder (as defined in "The Merger — Material U.S. Federal Income Tax Consequences of the Reverse Stock Split and the Merger" beginning on page 87 of this proxy statement) of NewLink's common stock generally should not recognize gain or loss upon the reverse stock split, except with respect to cash received in lieu of a fractional share of NewLink's common stock, as discussed in "The Merger — Material U.S. Federal Income Tax Consequences of the Reverse Stock Split and the Merger" beginning on page 87 of this proxy statement. For more information, see "The Merger — Material U.S. Federal Income Tax Consequences of the Reverse Stock Split and the Merger" beginning on page 87 of this proxy statement.

The Merger is intended to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (the "Code"). NewLink stockholders will not sell, exchange or dispose of any shares of NewLink's common stock as a result of the Merger. Thus, there should be no material U.S. federal income tax consequences to NewLink stockholders in respect of their NewLink stock as a result of the Merger.

Risk Factors (see page 17)

The Merger, including the possibility that the Merger may not be consummated, poses a number of risks to NewLink and its stockholders. In addition, both NewLink and Lumos are subject to various risks associated with their businesses and their industries, and the combined business will also be subject to those and other risks.

Regulatory Approvals (see page 86)

Neither NewLink nor Lumos is required to make any filings or to obtain approvals or clearances from any antitrust regulatory authorities in the United States or other countries to consummate the Merger. In the United States, NewLink must comply with applicable federal and state securities laws and Nasdaq rules and regulations in connection with the issuance of shares of NewLink's common stock in the Merger, including the filing with the SEC of this proxy statement.

Anticipated Accounting Treatment (see page 89)

The Merger will be treated by NewLink as a reverse merger with Lumos being deemed the acquiror for accounting purposes. Further, the Merger is to be accounted for as an asset acquisition rather than a business combination because the assets acquired and liabilities assumed from NewLink do not meet the definition of a business as defined by ASC 805, *Business Combinations* as NewLink does not contain the processes in place to generate outputs.

Reverse Stock Split (see page 101)

At the Special Meeting, NewLink stockholders will be asked to approve the amendment (the "Charter Amendment") to the amended and restated certificate of incorporation of NewLink to effect a reverse stock split of the issued and outstanding shares of NewLink's common stock. Upon the effectiveness of the Charter Amendment effecting the reverse stock split, the outstanding shares of NewLink's common stock will be combined into a lesser number of shares such that one share of NewLink's common stock will be issued for a specified number of shares, which shall be between five and nine, of outstanding NewLink's common stock, with the exact number within the range to be mutually agreed upon by NewLink and Lumos prior to the closing of the Merger. The proposed reverse stock split will not change the number of authorized shares, or the par value, of NewLink's common stock.

No Appraisal Rights (see page 104)

No appraisal rights are available to the holders of NewLink's common stock in connection with the Merger.

Selected Unaudited Pro Forma Condensed Combined Financial Information of NewLink and Lumos (see page 149)

The following unaudited pro forma condensed combined financial statements give effect to the Merger and were prepared in accordance with the regulations of the SEC. The unaudited pro forma condensed combined financial statements were prepared using the acquisition method of accounting under GAAP. For accounting purposes, Lumos is considered to be acquiring NewLink in the Merger. Lumos was determined to be the accounting acquirer based upon the terms of the

Merger Agreement and other factors including: (i) Lumos stockholders will own approximately 50% of outstanding common stock of the combined company immediately following the closing of the Merger, (ii) the board of directors of the combined company will consist of three members designated by NewLink, three members designated by Lumos and the combined company's board of directors will unanimously appoint a seventh member and (iii) the combined company will be led by Lumos' current chief executive officer and chief scientific officer, with other current members of senior management to include both Lumos and NewLink. For the purpose of these unaudited pro forma condensed combined financial statements, management of NewLink and Lumos have determined a preliminary estimated purchase price, calculated as described in Note 2 to the unaudited pro forma condensed combined financial statements. Further, the Merger is to be accounted for as an asset acquisition rather than a business combination because the assets acquired and liabilities assumed from NewLink do not meet the definition of a business as defined by ASC 805, *Business Combinations* as NewLink does not contain the processes in place to generate outputs. The net assets acquired and liabilities assumed in connection with the Merger are recorded at their estimated acquisition date fair values. A final determination of these estimated fair values will be based on the actual net assets of NewLink that exist as of the date of completion of the Merger.

The unaudited pro forma condensed combined balance sheet as of September 30, 2019 assumes that the Merger took place on September 30, 2019 and combines the historical balance sheets of NewLink and Lumos as of September 30, 2019. The unaudited pro forma condensed combined statements of operations for the nine months ended September 30, 2019 and for the year ended December 31, 2018 assume that the Merger took place as of January 1, 2018 and combine the historical results of NewLink and Lumos for the nine months ended September 30, 2019 and for the year ended December 31, 2018, respectively. The historical financial statements of NewLink and Lumos, which are provided (or incorporated by reference) elsewhere in this proxy statement, have been adjusted to give pro forma effect to events that are (i) directly attributable to the Merger, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results.

The selected unaudited pro forma condensed combined financial data are presented for illustrative purposes only and are not necessarily indicative of the combined financial position or results of operations of future periods or the results that actually would have been realized had the entities been a single entity during these periods. The selected unaudited pro forma condensed combined financial data as of and for the nine months ended September 30, 2019 and for the year ended December 31, 2018 are derived from the unaudited pro forma condensed combined financial information and should be read in conjunction with that information. For more information, please see the section titled "Unaudited Pro Forma Condensed Combined Financial Information" in this proxy statement.

Unaudited Pro Forma Condensed Combined Balance Sheet Data

	As of September 30, 2019
(in thousands)	
Cash and cash equivalents	$ 106,192
Working capital, net	92,184
Total assets	154,333
Total liabilities	24,677
Accumulated deficit	(57,806)
Total shareholders' equity	129,656

Unaudited Pro Forma Condensed Combined Statement of Operations

	For the Nine Months Ended September 30, 2019	**For the Year Ended December 30, 2018**
	(in thousands, except per share information)	
Total revenue	$ 503	$ 12,474
Research and development	22,002	54,447
General and administrative	19,865	31,751

Total operating expenses	41,867	86,198
Loss from operations	(41,364)	(73,724)
Net loss	(39,549)	(64,757)
Basic and diluted loss per share	$ (0.52)	$ (0.85)

Comparative Historical and Unaudited Pro Forma Per Share Data

The information below reflects the historical net loss and book value per share of NewLink's common stock and the historical net loss and book value per unit of Lumos' common stock in comparison with the unaudited pro forma net loss and book value per share after giving effect to the Merger on a pro forma basis. The unaudited pro forma net loss and book value per share does not give effect to the reverse stock split contemplated by the Reverse Stock Split Proposal.

You should read the tables below in conjunction with the audited and unaudited consolidated financial statements of NewLink and the related notes, the audited and unaudited financial statements of Lumos and the related notes, and the unaudited pro forma condensed combined financial information and notes related to such financial statements included elsewhere in or incorporated by reference into this proxy statement.

	Nine Months Ended September 30, 2019
NewLink Historical Per Share Data	
Net loss per share, basic and diluted	$ (0.93)
Book value per share	$ 2.48
Lumos Historical Per Share Data	
Net loss per share, basic and diluted	$ (0.94)
Book value per share	$ (6.31)
Combined Company Per Share Data	
Net loss per share, basic and diluted	$ (0.52)
Book value per share	$ 1.70
Lumos Unaudited Pro Forma Equivalent Per Share Data	
Net loss per share, basic and diluted	$ (0.19)
Book value per share	$ 0.17

QUESTIONS AND ANSWERS ABOUT THE SPECIAL MEETING AND THE MERGER

Except as specifically indicated, the following information and all other information contained in this proxy statement does not give effect to the reverse stock split described in Proposal 2.

The following questions and answers are intended to briefly address commonly asked questions as they pertain to the Special Meeting of Stockholders (the "Special Meeting") of NewLink Genetics Corporation ("NewLink", the "Company", "we" or "us"), the Agreement and Plan of Merger and Reorganization (as amended, the "Merger Agreement"), the merger contemplated therein and the proposals to be voted on at the Special Meeting.

These questions and answers may not address all questions that may be important to you as a stockholder. Please refer to the "Summary" beginning on page 1 and the more detailed information contained elsewhere in this proxy statement and the annexes to this proxy statement, each of which you should read carefully.

What is the Merger?

NewLink, Lumos Pharma, Inc., a privately-held Delaware corporation ("Lumos") and Cyclone Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company ("Merger Sub"), have entered into the Merger Agreement that contains the terms and conditions of the proposed business combination of NewLink and Lumos. Under the Merger Agreement, Merger Sub will merge with and into Lumos, with Lumos surviving as a wholly-owned subsidiary of NewLink (the "Merger"). Immediately following the effective time of the Merger (the "Effective Time"), NewLink stockholders will own approximately 50% of the outstanding common stock of the combined company ("combined company") and Lumos stockholders will own approximately 50% of the outstanding common stock of the combined company. Immediately following the Merger, the combined company will be renamed as Lumos Pharma, Inc. and Lumos will be renamed to a name mutually agreed upon by NewLink and Lumos.

For a more complete description of the Merger, see "The Merger Agreement" beginning on page 90 of this proxy statement.

What will happen to NewLink if, for any reason, the Merger with Lumos does not close?

NewLink has invested significant time and incurred, and expects to continue to incur, significant expenses related to the proposed Merger with Lumos. If we do not consummate the Merger, we may be subject to certain material risks, including, the following: (i) under certain circumstances, we may be required to pay a termination fee to Lumos of $2.0 million; (ii) the price of our common stock may decline and remain volatile; and (iii) certain costs related to the Merger, such as legal and accounting fees, must be paid even if the Merger is not completed. In addition, if the Merger is not completed and NewLink's board of directors (the "NewLink Board") determines to seek another business combination, it may not be able to find a third party willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the Merger. In such circumstances, the NewLink Board may elect to, among other things, seek to out-license or partner with respect to our product candidates, divest all or a portion of our business, or take the steps necessary to liquidate all of our business and assets, and in any such case, the terms of which may be less attractive to us and our stockholders than the terms of the Merger Agreement.

Why is NewLink proposing to merge with Lumos?

The NewLink Board considered a number of factors that supported its decision to approve the Merger Agreement. In the course of its deliberations, the NewLink Board also considered a variety of risks and other countervailing factors related to entering into the Merger Agreement.

For a more complete discussion of our reasons for the Merger, see "The Merger—NewLink's Reasons for the Merger" and "The Merger—Recommendations of the NewLink Board" beginning on pages 66 and 68, respectively, of this proxy statement.

What is required to consummate the Merger?

To consummate the Merger, NewLink stockholders must approve the issuance of NewLink's common stock pursuant to the Merger Agreement, as well as the resulting "change of control" of NewLink under The Nasdaq Stock Market LLC ("Nasdaq") rules (Proposal 1 – the "Merger Proposal"), which requires the affirmative vote of a majority of the votes cast affirmatively or negatively on the Merger Proposal. Lumos stockholders have already approved of the Merger and the Merger Agreement.

In addition to obtaining NewLink stockholder approval, each of the other closing conditions set forth in the Merger Agreement must be satisfied or waived in order to consummate the Merger.

For a more complete description of the closing conditions under the Merger Agreement, see "The Merger Agreement — Conditions to the Closing of the Merger" beginning on page 92 of this proxy statement.

What will NewLink stockholders receive in the Merger?

On a pro forma basis, based upon the number of shares of NewLink's common stock to be issued in the Merger, NewLink stockholders as of immediately prior to the Effective Time of the Merger will own approximately 50% of the outstanding common stock of the combined company and Lumos stockholders as of immediately prior to the Effective Time of the Merger will own approximately 50% of the outstanding common stock of the combined company, as further described under "The Merger Agreement — Exchange Ratios" beginning on page 91 of this proxy statement. In addition, based on the number of outstanding equity awards and shares of capital stock of each of NewLink and Lumos as of December 31, 2019, immediately following the Effective Time (i) holders of NewLink common stock and equity awards are expected to own approximately 51.2% of the fully-diluted common stock of the combined company and (ii) holders of Lumos capital stock and equity awards are expected to own approximately 48.8% of the fully-diluted common stock of the combined company. As of December 31, 2019 and based on the closing price of the NewLink common stock on Nasdaq on December 31, 2019, outstanding NewLink options to acquire 848,485 shares of NewLink common stock are out-of-the-money (out of a total of outstanding NewLink options to acquire 3,483,422 shares of NewLink common stock on such date).

What are the material federal income tax consequences of the Merger to me?

The Merger is intended to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (the "Code"). NewLink stockholders will not sell, exchange or dispose of any shares of NewLink's common stock as a result of the Merger. Thus, there should be no material U.S. federal income tax consequences to NewLink stockholders with respect to their NewLink stock as a result of the Merger.

For a more complete description of the tax consequences of the Merger, see "The Merger — Material U.S. Federal Income Tax Consequences of the Reverse Stock Split and the Merger" beginning on page 87 of this proxy statement.

Why is NewLink seeking stockholder approval to issue shares of NewLink's common stock to existing Lumos stockholders in the Merger?

Because NewLink's common stock is listed on Nasdaq, we are subject to Nasdaq rules. Rule 5635(a) of the Nasdaq rules requires stockholder approval with respect to issuances of NewLink's common stock, among other instances, when the shares to be issued are being issued in connection with the acquisition of the stock or assets of another company and are equal to 20% or more of the outstanding shares of NewLink's common stock before the issuance. Rule 5635(b) of the Nasdaq rules also requires stockholder approval when any issuance or potential issuance will result in a "change of control" of the issuer. Although Nasdaq has not adopted any rule on what constitutes a "change of control" for purposes of Rule 5635(b), Nasdaq has previously indicated that the acquisition of, or right to acquire, by a single investor or affiliated investor group, as little as 20% of the common stock (or securities convertible into or exercisable for common stock) or voting power of an issuer could constitute a change of control.

Based on an assumed Merger closing date of December 31, 2019, NewLink will be issuing approximately 37.3 million shares of its common stock to Lumos stockholders, and the common stock to be issued pursuant to the Merger Agreement will represent greater than 20% of its voting stock. Accordingly, NewLink is seeking stockholder approval of this issuance under Nasdaq rules.

What is the reverse stock split and why is it necessary?

Pursuant to the Merger Agreement, NewLink will effect a reverse stock split prior to the Effective Time of the Merger, at a reverse stock split ratio to be mutually agreed upon by NewLink and Lumos within the range approved by NewLink stockholders and publicly announced by NewLink, for the purpose of maintaining compliance with Nasdaq listing standards.

According to applicable Nasdaq rules, in order for NewLink's common stock to continue to be listed on Nasdaq following the Merger, NewLink must satisfy certain requirements established by Nasdaq, including a $4.00 per share minimum bid price. Based on NewLink's closing price as of November 19, 2019, NewLink expects that a reverse

stock split will be necessary in order to maintain the listing of NewLink's common stock on Nasdaq following the Merger. The NewLink Board expects that a reverse stock split of NewLink's common stock will increase the market price of NewLink's common stock so that NewLink is able to maintain compliance with the relevant Nasdaq listing requirements.

Accordingly, at the Special Meeting, NewLink stockholders will be asked to approve an amendment (the "Charter Amendment") to our amended and restated certificate of incorporation (the "Charter") to effect a reverse stock split of the issued and outstanding shares of NewLink's common stock (Proposal 2 – the "Reverse Stock Split Proposal"). For additional information, see "Proposal 2: Approval of the Reverse Stock Split Proposal" beginning on page 101.

What are the material federal income tax consequences of the reverse stock split to me?

The reverse stock split is expected to constitute a "recapitalization" for U.S. federal income tax purposes. As a result, a U.S. Holder (as defined in "The Merger — Material U.S. Federal Income Tax Consequences of the Reverse Stock Split and the Merger" beginning on page 87 of this proxy statement) of NewLink's common stock generally should not recognize gain or loss upon the reverse stock split, except with respect to cash received in lieu of a fractional share of NewLink's common stock, as discussed in "The Merger — Material U.S. Federal Income Tax Consequences of the Reverse Stock Split and the Merger" beginning on page 87 of this proxy statement. A U.S. Holder's aggregate tax basis in the shares of NewLink's common stock received pursuant to the reverse stock split should equal the aggregate tax basis of the shares of NewLink's common stock surrendered (excluding any portion of such basis that is allocated to any fractional share of NewLink's common stock), and such U.S. Holder's holding period in the shares of NewLink's common stock received should include the holding period in the shares of NewLink's common stock surrendered. U.S. Holders of shares of NewLink's common stock acquired on different dates and at different prices should consult their tax advisors regarding the allocation of the tax basis and holding period of such shares. For more information, see "The Merger — Material U.S. Federal Income Tax Consequences of the Reverse Stock Split and the Merger" beginning on page 87 of this proxy statement.

Why am I being asked to consider and cast a non-binding advisory vote to approve the compensation that may be paid or become payable to NewLink's named executive officers that is based on or otherwise relates to the Merger?

In July 2010, the SEC adopted rules that require companies to seek a non-binding advisory vote to approve certain compensation that may be paid or become payable to their named executive officers that is based on or otherwise relates to corporate transactions such as the Merger. In accordance with the rules promulgated under Section 14A of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), NewLink is providing its holders of common stock with the opportunity to cast a non-binding advisory vote on compensation that may be paid or become payable to NewLink's named executive officers in connection with the Merger (Proposal 3 – the "Compensation Proposal"). For additional information, see "Proposal 3: Approval of the Compensation Proposal" beginning on page 105.

What will happen if NewLink stockholders do not approve the non-binding Compensation Proposal?

The vote to approve the non-binding Compensation Proposal is a vote separate and apart from the other proposals. Approval of the non-binding Compensation Proposal is not a condition to completion of the Merger, and it is advisory in nature only, meaning that it will not be binding on NewLink, Merger Sub or Lumos. Accordingly, if the Merger Proposal and the Reverse Stock Split Proposal are approved by NewLink stockholders and the Merger is completed, the compensation that is based on or otherwise relates to the Merger will be payable to NewLink's named executive officers even if this proposal is not approved.

Why am I receiving this proxy statement?

You are receiving this proxy statement because you have been identified as a holder of our common stock as of the record date.

How do I attend the Special Meeting?

The Special Meeting will be held on March 17, 2020 at 9:00 a.m. local time at ISU Economic Development Core Facility, 1805 Collaboration Place, Ames, IA 50010. Information on how to vote in person at the Special Meeting is discussed below. However, you do not need to attend the Special Meeting to vote your shares. Instead, you may simply complete, sign and return the enclosed proxy card, or follow the instructions below or on the proxy card to submit your proxy via the telephone or the internet.

Who can vote at the Special Meeting?

Only stockholders of record as of February 7, 2020, or the record date, will be entitled to vote at the Special Meeting. On the record date, there were 37,328,425 shares of NewLink's common stock outstanding and entitled to vote.

Stockholder of Record: Shares Registered in Your Name

If on February 7, 2020, your shares were registered directly in your name with our transfer agent, Computershare Shareowner Services LLC, then you are a stockholder of record. As a stockholder of record, you may vote in person at the Special Meeting or vote by proxy. Whether or not you plan to attend the Special Meeting, we urge you to vote by proxy over the telephone or on the internet as instructed below, or to fill out and return the enclosed proxy card to ensure your vote is counted.

Beneficial Owner: Shares Registered in the Name of a Broker or Bank

If on February 7, 2020, your shares were held not in your name with our transfer agent, but rather in an account at a brokerage firm, bank, dealer or other similar organization, then you are the beneficial owner of shares held in "street name." The organization holding your account is considered to be the stockholder of record for purposes of voting at the Special Meeting. As a beneficial owner, you have the right to direct your broker, bank or other agent regarding how to vote the shares in your account in accordance with the instructions you have received from them. You are also invited to attend the Special Meeting. However, since you are not the stockholder of record, you may not vote your shares in person at the Special Meeting unless you request and obtain a valid proxy from your broker, bank or other agent that is the stockholder of record.

What am I voting on?

There are four matters scheduled for a vote:

1. The Merger Proposal
2. The Reverse Stock Split Proposal
3. The Compensation Proposal
4. To adjourn or postpone the Special Meeting, if necessary or appropriate, for the purpose of soliciting additional votes for the approval of the Merger Proposal or the Reverse Stock Split Proposal (the "Adjournment Proposal")

What if another matter is properly brought before the meeting?

We know of no other matters that will be presented for consideration at the Special Meeting. If any other matters are properly brought before the meeting, it is the intention of the persons named in the accompanying proxy to vote on those matters in accordance with their best judgment.

How do I vote?

For each of the proposal to be voted on, you may vote "FOR" or "AGAINST" or abstain from voting.

The procedures for voting are:

Stockholder of Record: Shares Registered in Your Name

If you are a stockholder of record, you may vote in person at the Special Meeting, vote by proxy over the telephone, vote by proxy through the internet, or vote by proxy using the enclosed proxy card. Whether or not you plan to attend the Special Meeting, we urge you to vote by proxy to ensure that your vote is counted. You may still attend the Special Meeting and vote in person even if you have already voted by proxy.

- To vote in person, come to the Special Meeting and we will give you a ballot when you arrive.
- To vote using the proxy card, simply complete, sign and date the enclosed proxy card and return it promptly in the envelope provided. If you return your signed proxy card to us before the meeting, we will vote your shares as you direct.
- To vote over the telephone, dial toll-free 1-800-690-6903 using a touch-tone phone and follow the recorded instructions. You will be asked to provide the control number from the enclosed proxy card. Your telephone vote must be received by 11:59 p.m., Eastern Time, on March 16, 2020 to be counted.
- To vote through the internet, go to www.proxyvote.com to complete an electronic proxy card. Have your proxy card in hand when you access the web site and follow the instructions to obtain your records and to create an electronic voting instruction form. Your internet vote must be received by 11:59 p.m., Eastern Time, on March 16, 2020 to be counted.

Beneficial Owner: Shares Registered in the Name of Broker or Bank

If you are a beneficial owner of shares registered in the name of your broker, bank or other agent, you should have received a voting instruction form accompanying the proxy materials containing voting instructions from that organization rather than from us. Simply follow the voting instructions in the voting instruction form to ensure that your vote is counted. To vote in person at the Special Meeting, you must obtain a valid proxy from your broker, bank or other agent. Follow the instructions from your broker or bank included with these proxy materials, or contact your broker or bank to request a proxy form.

Internet proxy voting may be provided to allow you to vote your shares online, with procedures designed to ensure the authenticity and correctness of your proxy vote instructions. However, please be aware that you must bear any costs associated with your internet access, such as usage charges from internet access providers and telephone companies.

How many votes do I have?

On each matter to be voted upon, you have one vote for each share of common stock you own as of February 7, 2020, the record date. Common stock is the only class of voting securities currently outstanding and entitled to vote.

What happens if I do not vote?

Stockholder of Record: Shares Registered in Your Name

If you are a stockholder of record and do not vote (1) by completing and returning your proxy card, (2) by telephone, (3) through the internet or (4) in person at the Special Meeting, your shares will not be voted.

Beneficial Owner: Shares Registered in the Name of Broker or Bank

If you are a beneficial owner and do not instruct your broker, bank, or other agent how to vote your shares, the question of whether your broker, bank or other agent will still be able to vote your shares depends on whether the New York Stock Exchange (NYSE) deems the particular proposal to be a “routine” matter. Brokers, banks and other agents can use their discretion to vote “uninstructed” shares with respect to matters that are considered to be “routine,” but not with respect to “non-routine” matters. Under the rules and interpretations of the New York Stock Exchange, “non-routine” matters are matters that may substantially affect the rights or privileges of stockholders, such as mergers, shareholder proposals, elections of directors (even if not contested), executive compensation (including any advisory shareholder votes on executive compensation and on the frequency of shareholder votes on

executive compensation), and certain corporate governance proposals, even if management-supported. These rules apply to brokers holding our shares even though our common stock is traded on The Nasdaq Global Market. Accordingly, your broker, bank or other agent may not vote your shares on Proposals 1 or 3 (Merger Proposal or Compensation Proposal), without your instructions, but may vote your shares on Proposals 2 or 4 (Reverse Stock Split Proposal or Adjournment Proposal) even in the absence of your instruction.

What if I return a proxy card or otherwise vote but do not make specific choices?

If you return a signed and dated proxy card or otherwise vote without marking voting selections, your shares will be voted, as applicable, "FOR" the Merger Proposal, "FOR" the Reverse Stock Split Proposal, "FOR" the Compensation Proposal, and "FOR" the Adjournment Proposal. If any other matter is properly presented at the meeting, your proxyholder (one of the individuals named on your proxy card) will vote your shares using his or her best judgment.

Who is paying for this proxy solicitation?

We will pay for the entire cost of soliciting proxies. In addition to these proxy materials, our directors and employees may also solicit proxies in person, by telephone, or by other means of communication. Directors and employees will not be paid any additional compensation for soliciting proxies. We have engaged The Proxy Advisory Group, LLC to assist in the solicitation of proxies and provide related advice and information support for a services fee and customary disbursements, which are not expected to exceed $50,000 in total. We may also reimburse brokerage firms, banks and other agents for the cost of forwarding proxy materials to beneficial owners.

What does it mean if I receive more than one set of proxy materials?

If you receive more than one set of proxy materials, your shares may be registered in more than one name or in different accounts. For example, you may own some shares directly as a stockholder of record and other shares through a broker, or you may own shares through more than one broker. In these situations, you will receive multiple sets of proxy materials. You must complete, sign, date and return all of the proxy cards or follow the instructions for any alternative voting procedures on each of the proxy cards you receive in order to vote all of the shares you own. Each proxy card you receive will come with its own postage-paid return envelope; if you vote by mail, make sure you return each proxy card in the return envelope that accompanied that proxy card.

Can I change my vote after submitting my proxy?

Stockholder of Record: Shares Registered in Your Name

Yes. You can revoke your proxy at any time before the final vote at the Special Meeting. If you are the record holder of your shares, you may revoke your proxy in any one of the following ways:

- You may submit another properly completed proxy card with a later date;
- You may grant a subsequent proxy by telephone or through the internet;
- You may send a timely written notice that you are revoking your proxy to our Secretary at 2503 South Loop Drive, Suite 5100, Ames, IA 50010; or
- You may attend the Special Meeting and vote in person (simply attending the meeting will not, by itself, revoke your proxy).

Your most current proxy card or telephone or internet proxy is the one that is counted.

Beneficial Owner: Shares Registered in the Name of Broker or Bank

If your shares are held by your broker or bank as a nominee or agent, you should follow the instructions provided by your broker or bank.

When are stockholder proposals due for next year's annual meeting?

To be considered for inclusion in next year's proxy materials, your proposal must have been submitted in writing and received by December 7, 2019 to Corporate Secretary, NewLink Genetics Corporation, 2503 South Loop Drive, Ames, Iowa 50010. If you wish to submit a director nomination or a proposal at next year's annual meeting that is not to be included in next year's proxy materials, you must do so by no later than the close of business on February 8, 2020, nor earlier than the close of business on January 9, 2020, and you must comply with the

requirements of Section 5(b) in our amended and restated bylaws (the "Bylaws"), including submitting written notice to our Corporate Secretary as set forth above. However, if the date of next year's annual meeting is more than 30 days before or more than 30 days after May 9, 2020, then we must receive your notice no earlier than the close of business on the one hundred twentieth (120th) day prior to such meeting and no later than the close of business on the later of the ninetieth (90th) day prior to such meeting or the tenth (10th) day following the day on which public announcement of the date of such meeting is first made. You are also advised to review our Bylaws, which contain additional requirements regarding advance notice of stockholder proposals and director nominations.

What happens if I do not provide instructions on how to vote or if other matters are presented for determination at the Special Meeting?

If you are a stockholder of record and return your proxy card without instructions, the persons named as proxy holders on the proxy card will vote in accordance with the recommendations of the NewLink Board.

If you are a beneficial owner as noted above you generally cannot vote your shares directly and must instead instruct your broker, bank or other agent how to vote your shares using the voting instructions form provided by that intermediary. If you do not provide voting instructions, whether your shares can be voted by your broker, bank or other agent depends on the type of item being considered.

- *Non-Discretionary Items*. If you do not provide voting instructions for any of the non-discretionary items at the Special Meeting, your broker, bank or other agent cannot vote your shares, resulting in a "broker non-vote." Proposals 1 and 3 (Merger Proposal and Compensation Proposal) are non-discretionary items. Shares constituting broker non-votes will be counted as present for the purpose of determining a quorum at the Special Meeting, but generally are not counted or deemed to be present in person or by proxy for the purpose of voting on any of the non-discretionary items.
- *Discretionary Items*. Even if you do not provide voting instructions, your broker, bank or other agent may vote in its discretion on Proposals 2 and 4 (Reverse Stock Split Proposal and Adjournment Proposal) because they are discretionary items.

What items are being voted upon, how does the NewLink Board recommend that you vote, and what are the standards for determining whether an item has been approved?

Proposal Number	Proposal Description	NewLink Board Recommendation	Vote Required for Approval	Effect of Abstentions	Effect of Broker Non-Vote
1	Merger Proposal	FOR	"FOR" votes from a majority of the votes cast	None	None
2	Reverse Stock Split Proposal	FOR	"FOR" votes from a majority of the outstanding shares entitled to vote	Against	Not Applicable
3	Compensation Proposal	FOR	"FOR" votes from a majority of the votes cast	None	None
4	Adjournment Proposal	FOR	"FOR" votes from a majority of the votes cast	None	Not Applicable

What is the quorum requirement?

A quorum of stockholders is necessary to hold a valid meeting. A quorum will be present if stockholders holding a majority of the outstanding shares entitled to vote are present at the meeting in person or represented by proxy. On the record date, there were 37,328,425 shares outstanding and entitled to vote. Thus, the holders of 18,664,213 shares must be present in person or represented by proxy at the meeting to have a quorum.

Your shares will be counted toward the quorum only if you submit a valid proxy (or one is submitted on your behalf by your broker, bank or other agent) or if you vote in person at the Special Meeting. Abstentions and broker non-votes will be counted towards the quorum requirement. If there is no quorum, the holders of a majority of shares present at the meeting in person or represented by proxy may adjourn the meeting to another date.

How can I find out the results of the voting at the Special Meeting?

Preliminary voting results will be announced at the Special Meeting. In addition, final voting results will be published in a current report on Form 8-K that we expect to file within four business days after the Special Meeting. If final voting results are not available to us in time to file a Form 8-K within four business days after the Special Meeting, we intend to file a Form 8-K to publish preliminary results and, within four business days after the final results are known to us, file an additional Form 8-K to publish the final results.

MARKET AND DIVIDEND INFORMATION

NewLink's common stock is listed on the Nasdaq under the symbol "NLNK."

Lumos is a private company and its capital stock is not publicly traded. There has never been, nor is there expected to be in the future, a public market for Lumos' capital stock. As of December 31, 2019, there were 30,174,234 shares of Lumos' common stock outstanding and held of record by 15 stockholders.

Following the Effective Time, and subject to successful application for initial listing with Nasdaq, NewLink's common stock will continue to be listed on Nasdaq, but will trade under the symbol "LUMO" and under the combined company's new name, "Lumos Pharma, Inc."

NewLink has never declared or paid and has no intention to declare or pay any cash dividends on its capital stock.

RISK FACTORS

You should consider the following factors in evaluating the Merger and whether to approve the proposals to be voted on at the Special Meeting. These factors should be considered in conjunction with the other information included or incorporated by reference by NewLink in this proxy statement.

Risks Related to the Merger

If the proposed Merger with Lumos is not consummated, our business could suffer materially, and our stock price could decline.

The consummation of the proposed Merger with Lumos is subject to a number of closing conditions, including the approval by NewLink stockholders and other customary closing conditions. We are targeting a closing of the Merger by the first quarter of 2020.

If the proposed Merger is not consummated, we may be subject to a number of material risks, and our business and stock price could be materially adversely affected, as follows:

- we may not be able to continue to operate NewLink on a stand-alone basis given current market sentiment toward indoleamine-2, 3-dioxygenase ("IDO") inhibitors as a class and the likelihood that market conditions for NewLink would not change for the benefit of NewLink stockholders in the foreseeable future on a stand-alone basis;
- we have incurred and expect to continue to incur significant expenses related to the proposed Merger with Lumos even if the Merger is not consummated;
- the Merger Agreement contains covenants relating to our solicitation of competing acquisition proposals and the conduct of our business between the date of signing the Merger Agreement and the closing of the Merger. Accordingly, we may be unable to pursue business opportunities that would otherwise be in our best interest as a standalone company;
- we may be obligated to pay Lumos a $2.0 million termination fee in connection with the termination of the Merger Agreement;
- our customers, manufacturers, partners and other investors in general may view the failure to consummate the Merger as a poor reflection on our business or prospects;
- some of our manufacturers and other business partners may seek to change or terminate their relationships with us as a result of the proposed Merger;
- as a result of the proposed Merger, current and prospective employees could experience uncertainty about their future roles within the combined company. This uncertainty may adversely affect our ability to retain our key employees, who may seek other employment opportunities;
- our workforce reduction costs may be greater than anticipated and our recent workforce reduction may have an adverse impact on our development activities;
- our management team may be distracted from day to day operations as a result of the proposed Merger; and
- the market price of our common stock may decline to the extent that the current market price reflects a market assumption that the proposed Merger will be completed.

In addition, if the Merger Agreement is terminated and the NewLink Board determines to seek another business combination, it may not be able to find a third party willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the Merger. In such circumstances, the NewLink Board may elect to, among other things, seek to out-license or partner with respect to our product candidates, divest all or a portion of our business, or take the steps necessary to liquidate all of our business and assets, and in either such case, the consideration that we receive may be less attractive than the consideration to be received by us pursuant to the Merger Agreement.

The exchange ratios are not adjustable based on the market price of NewLink's common stock so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.

Pursuant to the Merger Agreement, the applicable exchange ratios are included in Lumos' amended and restated certificate of incorporation ("Lumos' Charter"), which does not include a price-based termination right and there will

be no adjustment to the total number of shares of NewLink's common stock that Lumos stockholders and optionholders will be entitled to receive for changes in the market price of NewLink's common stock. Any changes in the market price of NewLink's common stock before the completion of the Merger will not affect the number of shares Lumos stockholders will be entitled to receive pursuant to the Merger Agreement. See also "The Merger Agreement — Exchange Ratios." Therefore, if before the completion of the Merger the market price of NewLink's common stock increases from the market price on the date of the Merger Agreement, then Lumos stockholders could receive merger consideration with substantially more value for their shares of Lumos capital stock than the parties had negotiated for in the establishment of the exchange ratios.

Failure to complete the Merger may result in NewLink paying a termination fee or expenses to Lumos and could harm the common stock price of NewLink and future business and operations of NewLink.

If the Merger is not completed, we are subject to the following risks:

- if the Merger Agreement is terminated under certain circumstances, we may be required to pay a termination fee to Lumos of $2,000,000;
- the price of our stock may decline and remain volatile; and
- significant costs related to the Merger, such as legal and accounting fees, which must be paid even if the Merger is not completed.

In addition, if the Merger Agreement is terminated and the NewLink Board determines to seek another business combination, there can be no assurance that we will be able to find a partner willing to provide equivalent or more attractive consideration than the consideration to be provided by Lumos.

If the conditions to the Merger are not met, the Merger may not occur.

Even if the Merger is approved by the NewLink stockholders, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement and described in "The Merger Agreement — Conditions to the Closing of the Merger" beginning on page 92 of this proxy statement. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or will be delayed, and we may lose some or all of the intended benefits of the Merger.

Some of NewLink's officers and directors have conflicts of interest that may influence them to support or approve the Merger.

Our officers and directors participate in arrangements that provide them with interests in the Merger, including, among others, their continued service as an officer or a director of the combined company, if applicable, retention and severance benefits, the acceleration of equity awards and continued indemnification. These interests, among others, may influence the officers and directors of NewLink to support or approve the Merger. For a more detailed discussion see "The Merger — Interests of NewLink's Directors and Executive Officers in the Merger" beginning on page 68 of this proxy statement.

The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes and other causes.

In general, either party can refuse to complete the Merger if there is a material adverse effect that has occurred between September 30, 2019, the date of the Merger Agreement, and the closing. However, some types of changes do not permit either party to refuse to complete the Merger, even if such changes would have a material adverse effect on NewLink or Lumos, to the extent they resulted from the following and do not have a materially disproportionate effect on NewLink or Lumos, as the case may be:

- changes in general business, economic or political conditions affecting the industry in which the parties operate generally;
- changes caused by any natural disaster or any acts of war, armed hostilities or terrorism;
- changes in financial, banking or securities markets;
- changes caused by the failure to meet internal or analysts' expectations or projections or the results of operations;

- changes resulting from any clinical trial programs or studies, including any adverse data, event or outcome arising out of or related to any such programs or studies;
- changes in, or compliance with or actions taken for the purpose of complying with, any law or U.S. generally accepted accounting principles ("GAAP") (or interpretations of any law or GAAP);
- changes resulting from the announcement or pendency of the Merger;
- changes resulting from the taking of any action, or failure to take any action, that is required to be taken by the Merger Agreement; or
- with respect to NewLink, a change in NewLink's stock price or trading volume.

If adverse effects occur but NewLink and Lumos must still complete the Merger, the combined company's stock price may suffer.

The market price of the combined company's common stock may decline as a result of the Merger.

The market price of the combined company's common stock may decline as a result of the Merger for a number of reasons including if:

- the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts;
- the effect of the Merger on the combined company's business and prospects is not consistent with the expectations of financial or industry analysts; or
- investors react negatively to the effect on the combined company's business and prospects from the Merger.

NewLink stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

If the combined company is unable to realize the strategic and financial benefits currently anticipated from the Merger, NewLink stockholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. Significant management attention and resources will be required to integrate the two companies. Delays in this process could adversely affect the combined company's business, financial results, financial condition and stock price following the Merger. Even if the combined company were able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time.

During the pendency of the Merger, NewLink may not be able to enter into a business combination with another party and will be subject to contractual limitations on certain actions because of restrictions in the Merger Agreement.

Covenants in the Merger Agreement impede the ability of NewLink to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the Merger. As a result, if the Merger is not completed, NewLink may be at a disadvantage to its competitors. In addition, while the Merger Agreement is in effect and subject to limited exceptions, each party is prohibited from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to the entering into certain extraordinary transactions with any third party, such as a sale of assets, an acquisition of NewLink's common stock, a tender offer for NewLink's common stock or a merger or other business combination outside the ordinary course of business. Any such transactions could be favorable to NewLink stockholders.

Because the lack of a public market for Lumos' capital stock makes it difficult to evaluate the fairness of the Merger, the value of NewLink's common stock to be issued in connection with the Merger may be greater than the fair market value of Lumos.

The outstanding share capital of Lumos is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Lumos. Since the percentage of NewLink's equity to be issued to Lumos stockholders was determined based on negotiations between the parties, it is possible that the value of NewLink's common stock to be issued in connection with the Merger will be greater than the fair market value of Lumos.

The combined company will incur significant transaction costs as a result of the Merger, including investment banking, legal and accounting fees. In addition, the combined company will incur significant consolidation and integration expenses which cannot be accurately estimated at this time. Actual transaction costs may substantially exceed our estimates and may have an adverse effect on the combined company's financial condition and operating results.

Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Code and the Merger is expected to result in a further limitation on our ability to utilize our net operating loss carryforwards and other tax attributes.

Sections 382 and 383 of the Code limit a corporation's ability to utilize its net operating loss carryforwards ("NOLs") and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State NOLs (and certain other tax attributes) may be similarly limited. A Section 382 ownership change can, therefore, result in significantly greater tax liabilities than a corporation would incur in the absence of such a change, and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

Based on Section 382 ownership change analyses, we believe that, from our inception through June 30, 2019, we experienced Section 382 ownership changes in September 2001 and March 2003, and our subsidiary, BioProtection Systems Corporation, experienced Section 382 ownership changes in January 2006 and January 2011. Furthermore, we will experience an ownership change as a result of the Merger and therefore our ability to utilize our NOLs and certain tax credit carryforwards remaining at the Effective Time will be limited. The limitation will be determined by the fair market value of our common stock outstanding prior to the ownership change, multiplied by the applicable federal rate.

These ownership changes limit our ability to utilize federal NOLs and certain other tax attributes that accrued prior to the respective ownership changes of us and our subsidiaries and may continue to limit our and our subsidiaries' ability to utilize such attributes in the future. Limitations imposed on our ability to utilize NOLs could cause U.S. federal and state income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause such NOLs to expire unused, in each case reducing or eliminating the benefit of such NOLs.

The opinion received by the NewLink Board from Stifel has not been, and is not expected to be, updated to reflect changes in circumstances that may have occurred since the date of the opinion.

At a meeting of the NewLink Board on September 30, 2019, NewLink's financial advisor, Stifel, Nicolaus & Company, Incorporated ("Stifel"), rendered its oral opinion, subsequently confirmed in writing by delivery of a written opinion, to the NewLink Board that, as of that date and based upon and subject to the factors, limitations and assumptions set forth in its opinion, the merger consideration to be paid by NewLink (the "Merger Consideration") in the Merger pursuant to the Merger Agreement was fair to NewLink from a financial point of view. The opinion does not speak as of the time the Merger will be completed or any date other than the date of such opinion. The opinion does not reflect changes that may occur or may have occurred after the date of the opinion, including changes to the operations and prospects of NewLink or Lumos, changes in general market and economic conditions or regulatory or other factors. Any such changes may materially alter or affect the relative values of NewLink and Lumos. Stifel does not have any obligation to update, revise or reaffirm its opinion to reflect subsequent developments and has not done so.

Subsequent to the delivery of Stifel's opinion, NewLink's management discovered that, as a result of a previous amendment to the agreement between NewLink and the Public Health Agency of Canada that management inadvertently did not provide to Stifel, NewLink is not required to make a payment to the Public Health Agency of Canada in connection with the sale of the PRV. Upon discovery of this omission, management of NewLink consulted with Stifel regarding the impact, if any, that this information would have had on Stifel's opinion had Stifel been in possession of such information at the time it rendered its opinion. Based upon this additional information, Stifel calculated that, as of the date of its opinion, and based upon the valuation methodology employed by Stifel to value the PRV, the implied equity value of NewLink would be between $3.1 million and $4.4 million higher, or between approximately 2.5% and 3.2% higher, respectively. Stifel indicated that, had it been in possession of such information at the time it rendered its opinion, subject to the assumptions, qualifications and limitations set forth in the opinion, it would have reached the same conclusion. Stifel was not asked to update or reaffirm its opinion to account for any subsequent events occurring after the date of its opinion.

See also "The Merger — Opinion of NewLink's Financial Advisor" beginning on page 72 and *Annex F* to this proxy statement.

Certain stockholders could attempt to influence changes within us that could adversely affect our operations, financial condition and the value of our common stock.

Our stockholders may from time to time seek to acquire a controlling stake in NewLink, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes. Campaigns by stockholders to effect changes at publicly-traded companies are sometimes led by investors seeking to increase short-term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases or sales of assets or the entire company. Responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, and could disrupt our operations and divert the attention of the NewLink Board and senior management from the pursuit of the proposed Merger transaction. These actions could adversely affect our operations, financial condition, ability to consummate the Merger and the value of our common stock.

We may become involved in securities litigation or stockholder derivative litigation in connection with the Merger, and this could divert the attention of management and harm the combined company's business, and insurance coverage may not be sufficient to cover all related costs and damages.

Securities litigation or stockholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. We may become involved in this type of litigation in connection with the Merger, and the combined company may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect the business of NewLink and the combined company.

Risks Related to the Reverse Stock Split

The reverse stock split may not increase our stock price over the long term.

The principal purpose of the reverse stock split is to increase the per-share market price of our common stock. It cannot be assured, however, that the reverse stock split will accomplish this objective for any meaningful period of time. While it is expected that the reduction in the number of outstanding shares of our common stock will proportionally increase the market price of our common stock, it cannot be assured that the reverse stock split will increase the market price of our common stock by a multiple of the reverse stock split ratio to be mutually agreed upon by us and Lumos, or result in any permanent or sustained increase in the market price of our common stock, which is dependent upon many factors, including our business and financial performance, general market conditions, and prospects for future success. Thus, while the stock price of the combined company might meet the continued listing requirements for Nasdaq initially, it cannot be assured that it will continue to do so.

The reverse stock split may decrease the liquidity of our common stock.

Although the NewLink Board believes that the anticipated increase in the market price of our common stock could encourage interest in its common stock and possibly promote greater liquidity for its stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the reverse stock split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for our common stock.

The reverse stock split may lead to a decrease in our overall market capitalization.

Should the market price of our common stock decline after the reverse stock split, the percentage decline may be greater, due to the smaller number of shares outstanding, than it would have been prior to the reverse stock split. A reverse stock split is often viewed negatively by the market and, consequently, can lead to a decrease in our overall market capitalization. If the per share market price does not increase in proportion to the reverse stock split ratio, then the value of the combined company, as measured by its stock capitalization, will be reduced. In some cases, the per-share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse split levels, and accordingly, it cannot be assured that the total market value of our common stock will remain the same after the reverse stock split is effected, or that the reverse stock split will not have an adverse effect on our stock price due to the reduced number of shares outstanding after the reverse stock split.

Risks Related to NewLink

NewLink is, and will continue to be, subject to the risks described in "Risk Factors" contained in our most recent annual report on Form 10-K and our most recent quarterly report on Form 10-Q, as well as any amendments thereto reflected in subsequent filings with the SEC, which are incorporated by reference into this proxy statement. See "Where You Can Find More Information," beginning on page 166.

Risks Related to Lumos' Financial Condition and Capital Requirements

Lumos has a limited operating history and has incurred significant losses since its inception, and Lumos anticipates that it will continue to incur substantial and increasing losses for the foreseeable future. Lumos has only one product candidate and no commercial sales, which, together with its limited operating history, makes it difficult to evaluate its business and assess its future viability.

Lumos is a clinical-stage biopharmaceutical company with a limited operating history. Lumos does not have any products approved for sale, and is currently focused on developing its only product candidate, the growth hormone ("GH") secretagogue ibutamoren ("LUM-201," previously MK-0677 and L-163,191). Evaluating Lumos' performance, viability or future success will be more difficult than if it had a longer operating history or approved products on the market. Lumos continues to incur significant research and development and general and administrative expenses related to its operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. Lumos has incurred significant operating losses in each year since its inception and expects to incur substantial and increasing losses for the foreseeable future. As of September 30, 2019, Lumos had an accumulated deficit of $56.5 million.

To date, Lumos has financed its operations primarily through private placements of its convertible preferred stock. Lumos has devoted substantially all of its efforts to research and development, including clinical trials, but has not completed development of any product candidate. Lumos anticipates that its expenses will increase substantially as it:

- continues the research and development of its only product candidate, LUM-201, and any future product candidates;
- continues clinical trials of LUM-201, including the Phase 2b clinical trial of LUM-201 (the "Phase 2b Trial") that it expects to initiate in mid-2020;
- seeks to in-license additional product candidates;
- seeks regulatory approvals for LUM-201 and any future product candidates that successfully complete clinical trials;
- establishes a sales, marketing and distribution infrastructure and scales-up manufacturing capabilities to commercialize LUM-201 or other future product candidates if they obtain regulatory approval, including process improvements in order to manufacture LUM-201 or other future product candidates at commercial scale; and
- enhances operational, financial and information management systems and hires more personnel, including personnel to support development of LUM-201 and any future product candidates and, if a product candidate is approved, its commercialization efforts.

To be profitable in the future, Lumos must succeed in developing and eventually commercializing LUM-201 as well as other products with significant market potential. This will require Lumos to be successful in a range of activities, including advancing LUM-201 and any future product candidates, completing clinical trials of these product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which it may obtain regulatory approval. Lumos is only in the preliminary stages of some of these activities. Lumos may not succeed in these activities and may never generate revenue that is sufficient to be profitable in the future. Even if Lumos is profitable, it may not be able to sustain or increase profitability on a quarterly or annual basis. Lumos' failure to achieve sustained profitability would depress the value of Lumos and could impair its ability to raise capital, expand its business, diversify its product candidates, market its product candidates, if approved, or continue its operations.

Lumos currently has no source of product revenue and may never become profitable.

To date, Lumos has not generated any revenues from commercial product sales, or otherwise. Even if Lumos is able to successfully achieve regulatory approval for LUM-201 or any future product candidates, Lumos does not know when any of these products will generate revenue from product sales. Lumos' ability to generate revenue from product sales and achieve profitability will depend upon its ability, alone or with any future collaborators, to successfully commercialize products, including LUM-201 or any product candidates that it may develop, in-license or acquire in the future. Lumos' ability to generate revenue from product sales from LUM-201 or any future product candidates also depends on a number of additional factors, including Lumos' or any future collaborators' ability to:

- complete development activities, including its planned Phase 2b and Phase 3 clinical trials of LUM-201, successfully and on a timely basis;
- demonstrate the safety and efficacy of LUM-201 to the satisfaction of the U.S. Food and Drug Administration (the "FDA") and obtain regulatory approval for LUM-201 and future product candidates, if any, for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- set a commercially viable price for Lumos' products;
- establish and maintain supply and manufacturing relationships with reliable third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop a commercial organization capable of sales, marketing and distribution of any products for which it obtains marketing approval in markets where it intends to commercialize independently;
- find suitable distribution partners to help it market, sell and distribute its approved products in other markets;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- achieve market acceptance of its approved products, if any;
- establish, maintain and protect its intellectual property rights and avoid third-party patent interference or patent infringement claims; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that LUM-201 or any future product candidates may not advance through development or achieve the endpoints of applicable clinical trials, Lumos is unable to predict the timing or amount of increased expenses, or when or if it will be able to achieve or maintain profitability. In addition, Lumos' expenses could increase beyond expectations if it decides to or is required by the FDA or foreign regulatory authorities to perform studies or trials in addition to those that it currently anticipates. Even if Lumos is able to complete the development and regulatory process for LUM-201 or any future product candidates, it anticipates incurring significant costs associated with commercializing these products.

Even if Lumos is able to generate revenues from the sale of LUM-201 or any future product candidates that may be approved, Lumos may not become profitable and may need to obtain additional funding to continue operations. If Lumos fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and be forced to reduce or shut down its operations.

Lumos' operating results may fluctuate significantly, which makes its future operating results difficult to predict and could cause its operating results to fall below expectations or its guidance.

Lumos' quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for Lumos to predict its future operating results. From time to time, Lumos may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties. Accordingly, Lumos' revenue may depend on development funding and the achievement of development and clinical milestones under any potential future collaboration and license agreements and sales of its product candidates, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in its operating results from one period to the next. In addition, Lumos measures compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by its board of directors, and recognizes the cost as an expense over the employee's requisite service period. As the

variables that Lumos uses as a basis for valuing these awards change over time, the magnitude of the expense that it must recognize may vary significantly. Furthermore, Lumos' operating results may fluctuate due to a variety of other factors, many of which are outside of its control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to LUM-201 and any future product candidates, which will change from time to time;
- its ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing LUM-201 and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of its agreements with manufacturers;
- expenditures that it will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical trials for LUM-201 and any future product candidates or competing product candidates;
- changes in the competitive landscape of its industry, including consolidation among its competitors or partners;
- any delays in regulatory review or approval of LUM-201 or any of its future product candidates;
- the level of demand for LUM-201 and any future product candidates, should they receive approval, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to its products candidates, if approved, and existing and potential future drugs that compete with its product candidates;
- competition from existing and potential future drugs that compete with LUM-201 or any of its future product candidates;
- its ability to commercialize LUM-201 or any future product candidate inside and outside of the United States, either independently or working with third parties;
- its ability to establish and maintain collaborations, licensing or other arrangements;
- its ability to adequately support future growth;
- potential unforeseen business disruptions that increase its costs or expenses;
- future accounting pronouncements or changes in its accounting policies; and
- the changing and volatile global economic environment.

The cumulative effects of these factors could result in large fluctuations and unpredictability in Lumos' quarterly and annual operating results. As a result, comparing the operating results of Lumos on a period-to-period basis may not be meaningful. Investors should not rely on Lumos' past results as an indication of its future performance.

Lumos will need additional funds to support its operations, and such funding may not be available to it on acceptable terms, or at all, which would force it to delay, reduce or suspend its research and development programs and other operations or commercialization efforts. Raising additional capital may subject Lumos to unfavorable terms, cause dilution to its existing stockholders, restrict its operations or require it to relinquish rights to its product candidates and technologies.

The completion of the development and the potential commercialization of LUM-201 and any future product candidates, should they receive approval, will require substantial funds. Lumos' future financing requirements will depend on many factors, some of which are beyond its control, including the following:

- the rate of progress and cost of its clinical trials;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient, cost-effective, and scalable manufacturing process for LUM-201 and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties to obtain finished products that are appropriately packaged for sale;

- the costs of commercialization activities if LUM-201 or any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by Lumos or future partners;
- a continued acceptable safety profile following any marketing approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- Lumos' ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements;
- the emergence of competing technologies or other adverse market developments; and
- the costs of attracting, hiring and retaining qualified personnel.

Lumos does not have any material committed external source of funds or other support for its development efforts. Until Lumos can generate a sufficient amount of product revenue to finance its cash requirements, which it may never do, it expects to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. Additional financing may not be available to Lumos when it needs it or such additional financing may not be available on favorable terms. If Lumos raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, it may have to relinquish certain valuable rights to LUM-201 or potential future product candidates, technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to Lumos. If Lumos raises additional capital through public or private equity offerings, the ownership interest of its existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect its stockholders' rights. If Lumos raises additional capital through debt financing, it may be subject to covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If Lumos is unable to obtain adequate financing when needed, it may have to delay, reduce the scope of, or suspend one or more of its clinical trials or research and development programs or its commercialization efforts.

Risks Related to the Development and Commercialization of Lumos' Product Candidate

Lumos' success depends heavily on the successful development, regulatory approval and commercialization of its only product candidate, LUM-201.

Lumos does not have any products that have gained regulatory approval. Lumos' current clinical-stage product candidate is LUM-201 an orally-formulated GH stimulating therapeutic for a subset of pediatric growth hormone deficiency ("PGHD") patients and potentially other endocrine disorders. As a result, Lumos' near-term prospects, including its ability to finance its operations and generate revenue, are substantially dependent on its ability to obtain regulatory approval for and, if approved, to successfully commercialize LUM-201 in a timely manner.

Lumos cannot commercialize LUM-201 or any future product candidates in the United States without first obtaining regulatory approval for the product from the FDA, nor can it commercialize LUM-201 or any future product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. The FDA review process typically takes years to complete and approval is never guaranteed. Before obtaining regulatory approvals for the commercial sale of LUM-201 for a target PGHD indication or Lumos' future product candidates, Lumos generally must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical trials that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Lumos is pursuing the same regulatory pathway for LUM-201 followed by most of the approved recombinant human growth hormone ("rhGH") products and long-acting GH products under development for a subset of PGHD patients. Lumos intends to study treatment naïve and previously-treated patients by conducting trials including a six-month Phase 2b dose-finding trial and a Phase 3 clinical trial with a primary endpoint of 12 month mean height velocity that is intended to support regulatory approval. If Lumos must conduct additional or different trials than prior rhGH products were required to complete, this could increase the amount of time and expense required for regulatory approval of LUM-201, if any. In addition, while the available growth data from published studies of approved rhGH therapy products suggest that six and 12 months mean height velocities are well correlated, it is possible that LUM-201, due to its unique properties, will

produce different results. If the six months mean height velocities that Lumos observes for LUM-201 in the planned Phase 2b Trial do not correlate to 12 month mean height velocities that it ultimately observes in any Phase 3 clinical trial that it may conduct, LUM-201 may not achieve the required primary endpoint in the Phase 3 clinical trial, and LUM-201 may not receive regulatory approval. Moreover, obtaining regulatory approval for marketing of LUM-201 in one country does not ensure Lumos will be able to obtain regulatory approval in other countries, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

Even if LUM-201 or any of Lumos' future product candidates were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If Lumos is unable to obtain regulatory approval for LUM-201 in one or more jurisdictions, or any approval contains significant limitations, it may not be able to obtain sufficient funding or generate sufficient revenue to continue to fund its operations. Also, any regulatory approval of LUM-201 or its future product candidates, once obtained, may be withdrawn. Furthermore, even if Lumos obtains regulatory approval for LUM-201, the commercial success of LUM-201 will depend on a number of factors, including the following:

- development of Lumos' own commercial organization or establishment of a commercial collaboration with a commercial infrastructure;
- establishment of commercially viable pricing and obtaining approval for adequate reimbursement from third-party and government payors;
- the ability of Lumos' third-party manufacturers to manufacture quantities of LUM-201 using commercially viable processes at a scale sufficient to meet anticipated demand and reduce its cost of manufacturing, and that are compliant with the FDA's current Good Manufacturing Practices ("cGMP");
- Lumos' success in educating physicians and patients about the benefits, administration and use of LUM-201;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the effectiveness of Lumos' own or its potential strategic collaborators' marketing, sales and distribution strategy and operations;
- acceptance of LUM-201 as safe and effective by patients, caregivers and the medical community;
- a continued acceptable safety profile of LUM-201 following approval; and
- continued compliance with Lumos' obligations in its intellectual property licenses with third parties upon favorable terms.

Many of these factors are beyond Lumos' control. If Lumos or its commercialization collaborators are unable to successfully commercialize LUM-201, Lumos may not be able to earn sufficient revenues to continue its business.

The analysis that supports Lumos' basis for pursuing development of LUM-201 for PGHD is derived from data from three clinical trials conducted by Merck in the 1990s, and a post-hoc analysis of one of the trials. Various issues relating to such trials and analysis could materially adversely impact Lumos' LUM-201 clinical trial design and its future development plans.

The probability of the Phase 2b Trial succeeding is highly dependent on the adequacy of the Phase 2b Trial design. In designing such trial, Lumos reviewed data and analysis from three studies on LUM-201 completed by Merck in the 1990s (the "Merck Trials") and Lumos incorporated the results of Merck's analysis into the design of the Phase 2b Trial. However, Lumos could have misinterpreted or performed a flawed analysis of such data. Factors that could have affected Lumos' interpretation and analysis of the Merck Trials include:

- clinical trial procedures and statistical analysis methods may have changed since the 1990s when the Merck Trials were conducted, which limits Lumos' ability to effectively predict how changes to trial design might affect the Phase 2b Trial results;
- two of the Merck Trials were discontinued prior to completion due to lack of efficacy;

- one of the Merck Trials changed the formulation of the drug part way through the treatment naïve patient trial and for the other previously-treated patient trial the formulation change was for the entire trial, and the changed formulation was subsequently determined to have 30% to 40% less bioavailability;
- certain relevant information from the Merck Trials, including the source documentation for the Merck Trials, is not available and so could not be referenced for Lumos' analysis and Phase 2b Trial design; and
- bias in small sample size and other limitations inherent in the post-hoc analysis of the Merck Trials upon which Lumos has relied for its Phase 2b Trial design that could have caused such post-hoc analysis to be unreliable.

As a result of such factors, among others, there could be flaws in the design of the Phase 2b Trial that could cause it to fail, which would materially adversely impact Lumos' business, future development plans, and prospects.

Because the results of preclinical testing or earlier clinical trials are not necessarily predictive of future results, LUM-201 may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. Lumos does not know whether the clinical trials it is conducting, or may conduct, will demonstrate adequate efficacy and safety to result in regulatory approval to market LUM-201. Even if Lumos believes that it has adequate data to support an application for regulatory approval to market its product candidates, the FDA, the European Medicines Agency (the "EMA"), or other applicable foreign regulatory authorities may not agree and may require that Lumos conducts additional clinical trials. If later-stage clinical trials do not produce favorable results, Lumos' ability to achieve regulatory approval for LUM-201 may be adversely impacted.

There can be no assurance that LUM-201 will not exhibit new or increased safety risks in the Phase 2b Trial compared to the previously conducted Merck Trials, or, if it completes the Phase 2b Trial, in the planned Phase 3 clinical trial. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many other companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the marketing of their products.

In addition, Lumos has not yet established the optimal dose for LUM-201. There can be no guarantee that the three dose levels currently being planned in the Phase 2b Trial will be efficacious or, if they are, whether any one will be the optimal dose. The Phase 2b Trial may not be successful in determining a dose or dose regimen of LUM-201 suitable for future development and potential marketing approval.

As an organization, Lumos has never conducted a Phase 2b or a Phase 3 clinical trial or submitted a New Drug Application (an "NDA") before, and may be unsuccessful in doing so for LUM-201.

Lumos is currently planning to conduct the Phase 2b Trial and it may need to conduct additional clinical trials before initiating its planned Phase 3 clinical trial. If the Phase 2b Trial is successful, Lumos intends to independently conduct a Phase 3 clinical trial of LUM-201. To conduct a Phase 3 clinical trial and submit a successful NDA is a complicated process. As an organization, Lumos has never conducted a Phase 3 clinical trial, has limited experience in preparing, submitting and prosecuting regulatory filings, and has not submitted an NDA before. Lumos also has had limited interactions with the FDA and has not discussed any proposed clinical trial designs or implementations with the FDA. Consequently, even if the Phase 2b Trial is successful, Lumos may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to an NDA submission and approval of LUM-201. Failure to commence or complete, or delays in, Lumos' planned clinical trials would prevent Lumos from or delay it in commercializing LUM-201.

Delays in the enrollment of patients in any of Lumos' clinical trials could increase its development costs and delay completion of the trial.

Lumos may not be able to initiate or continue clinical trials for LUM-201 or any future product candidates if it is unable to locate and enroll a sufficient number of eligible patients to participate in these trials. Even if Lumos is able to enroll a sufficient number of patients in its clinical trials, if the pace of enrollment is slower than it expects, the development costs for its product candidates may increase and the completion of its trials may be delayed or its trials could become too expensive to complete.

There may be concurrent competing PGHD clinical trials that will inhibit or slow Lumos' enrollment in the planned Phase 2b and Phase 3 clinical trials. If Lumos experiences delays in enrollment, its ability to complete its planned clinical trials could be impaired and the costs of conducting such trials could increase, either of which could have a material adverse effect on its business.

If clinical trials of LUM-201 and any future product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, Lumos may incur additional costs, experience delays in completing or ultimately fail in completing the development and commercialization of LUM-201 or Lumos' future product candidates.

Before obtaining regulatory approval for the sale of any product candidate, Lumos must conduct extensive clinical trials to demonstrate the safety and efficacy of its product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more of Lumos' clinical trials could occur at any stage of testing.

Lumos has identified several aspects of the Phase 2b Trial protocols that could potentially delay or prevent its ability to receive regulatory approval or commercialize LUM-201. For example, Lumos may be administering LUM-201 at dose levels that are not as efficacious and/or safe as other rhGH therapies. The Phase 2b Trial will test doses of LUM-201 that are equal to, and two and four times higher than, the highest doses tested in the multiple dose Merck Trials. These higher doses were never tested in adults or children in a multiple dose trial in the Merck Trials and, even if the trials are able to show that such higher doses increase efficacy, such higher doses may not be as safe as the doses tested in the Merck Trials. As a result, Lumos may be required to test such higher doses in adults prior to being used in the Phase 2b Trial in children and frequent safety assessments may be required during the trial. Also, the Phase 2b Trial includes parallel dosing, a critical component in the trial design in order to identify optimal dosing, which may not be allowed by the FDA. The FDA may request staggered cohorts or staggered sentinel dosing, which could increase the duration and cost of the trial. In addition, the active pharmaceutical ingredient to be used in the Phase 2b Trial was manufactured by Merck approximately 15 years prior to the planned start of the trial and may not be approved for use by the FDA, even if it meets all necessary stability and other requirements or parents of patients to be included in the trial may have concerns about the age of the material. Also, the lack of source documentation from the Merck Trials may be a factor that delays approval of the FDA's IND program for the Phase 2b Trial.

In addition to trial design factors, Lumos may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent its ability to receive regulatory approval or commercialize LUM-201 or any future product candidates, including the following:

- clinical trials may produce negative or inconclusive results, and Lumos may decide, or regulators may require it, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials may be larger than Lumos anticipates, enrollment of subjects who meet Lumos' inclusion criteria in these clinical trials may be insufficient or slower than Lumos anticipates, or patients may drop out of these clinical trials at a higher rate than Lumos anticipates;
- the cost of clinical trials or the manufacturing of Lumos' product candidates may be greater than it anticipates;
- Lumos' third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to Lumos in a timely manner, or at all;
- Lumos might have to suspend or terminate clinical trials of its product candidates for various reasons, including a finding that its product candidates have unanticipated serious adverse events or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;
- regulators may not approve Lumos' proposed clinical development plans;
- regulators or institutional review boards may not authorize Lumos or its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- regulators or institutional review boards may require that Lumos or its investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the supply or quality of Lumos' product candidates or other materials necessary to conduct clinical trials of its product candidates may be insufficient or inadequate.

If Lumos is required to conduct additional clinical trials or other testing of LUM-201 or any future product candidates beyond those that it contemplates, if Lumos is unable to successfully complete clinical trials or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, Lumos may:

- be materially delayed in obtaining marketing approval for LUM-201 or other product candidates;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended or targeted;
- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed or used.

Lumos' product development costs will also increase if it experiences delays in testing or approvals. Lumos does not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all.

Significant clinical trial delays also could shorten any periods during which Lumos may have the exclusive right to commercialize its product candidates or allow its competitors to bring products to market before it does, which would impair Lumos' ability to commercialize its product candidates and harm its business and results of operations.

Even if Lumos obtains marketing approval for LUM-201, certain factors may limit the market for LUM-201, which could materially impair Lumos' ability to generate revenue from such product.

Even if Lumos receives regulatory approval for LUM-201, certain factors may limit the market for LUM-201 or put the product at a competitive disadvantage relative to alternative therapies. For instance, Lumos believes that the treatment will only be effective for approximately 50% to 60% of PGHD patients, and approximately 50% for patients with either SGA or Turner Syndrome, and the actual percentages could be substantially lower. Certain jurisdictions such as Australia and the European Union have different diagnostic criteria for diagnosing PGHD and as a result, the market for LUM-201 in those jurisdictions is smaller. In addition, there are a number of challenges that LUM-201 would face to obtain acceptance and use by physicians. Physicians will need to conduct additional testing to identify their patients who would be eligible for LUM-201 treatment. Approved products that would compete with LUM-201 have been used for many years or decades with an excellent safety profile. It will take a number of years of results of LUM-201 to provide the comfort level that may be necessary to satisfy some physicians and patient families. Some physicians may feel the benefits of an oral product do not outweigh limitations. For example, the mean annual growth velocity for LUM-201 treated patients included in the trial (PEM-Positive) may be substantially lower, despite meeting non-inferiority study requirements, than such mean for all rhGH treated PGHD patients. These factors could limit the size of the market LUM-201 intends to address and the rate of market acceptance, which could materially impair Lumos' ability to generate revenue.

LUM-201 or Lumos' future product candidates may cause serious adverse events or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any marketing approval.

Lumos' product candidate, LUM-201, has not completed clinical development. The risk of failure of clinical development is high. It is impossible to predict when or if this or any future product candidates will prove safe enough to receive regulatory approval. Undesirable adverse events caused by LUM-201 or any future product candidates could cause Lumos or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority.

At the doses tested previously in the Merck Trials, LUM-201 was generally well-tolerated in children with the most commonly reported adverse events being digestive systems events, including appetite increase. Mild elevations in liver enzymes without accompanying changes in bilirubin were also reported. To the knowledge of Lumos, no serious drug-related adverse events have been reported in children treated with LUM-201 to date. However, Lumos cannot assure you that adverse events from LUM-201 in current or future clinical trials will not prompt the discontinuation of the development of LUM-201. Similarly, Lumos' future product candidates may cause serious adverse events or have other properties that could delay or prevent their regulatory approval. As a result of these

adverse events or further safety or toxicity issues that Lumos may experience in its clinical trials in the future, it may not receive approval to market LUM-201 or any future product candidates, which could prevent Lumos from ever generating revenue or achieving profitability. Results of Lumos' trials could reveal an unacceptably high severity or prevalence of adverse events. In such an event, Lumos' trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order it to cease further development of or deny approval of its product candidates for any or all targeted indications. Any drug-related adverse events could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on Lumos' business, results of operations, financial condition, cash flows and future prospects.

Additionally, if LUM-201 or any of Lumos' future product candidates receive marketing approval, and Lumos or others later identify undesirable adverse events caused by such product, a number of potentially significant negative consequences could result, including:

- Lumos may be forced to suspend the marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of Risk Evaluation Mitigation Strategies ("REMS"), or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of Lumos' products and impose burdensome implementation requirements on Lumos;
- Lumos may be required to change the way the product is administered or conduct additional clinical trials;
- Lumos could be sued and held liable for harm caused to subjects or patients;
- Lumos may be subject to litigation or product liability claims; and
- Lumos' reputation may suffer.

Any of these events could prevent Lumos from achieving or maintaining market acceptance of the particular product candidate, if approved.

Even if Lumos' clinical trials demonstrate acceptable safety and efficacy of LUM-201 for growth in PGHD patients based on a once daily oral dosing regimen, the FDA or similar regulatory authorities outside the United States may not approve LUM-201 for marketing or may approve it with restrictions on the label, which could have a material adverse effect on Lumos' business, financial condition, results of operations and growth prospects.

Assuming the success of Lumos' clinical trials, it anticipates seeking regulatory approval for LUM-201 initially in the United States and the European Union for treatment of a subset of PGHD patients based on a once daily weight-based dosing regimen. Lumos may subsequently seek regulatory approval in other jurisdictions including China and Japan. It is possible that the FDA, the EMA, or regulatory agencies in other countries may not consider the results of Lumos' clinical trials to be sufficient for approval of LUM-201 for this indication. In general, the FDA suggests that sponsors complete two adequate and well-controlled clinical trials to demonstrate effectiveness because a conclusion based on two persuasive trials will be more compelling than a conclusion based on a single trial. Even if Lumos achieves favorable results in the Phase 2b Trial and its planned Phase 3 clinical trial and considering that LUM-201 is a new chemical entity, the FDA may nonetheless require that Lumos conduct additional clinical trials, possibly using a different clinical trial design.

Moreover, even if the FDA or other regulatory authorities approve LUM-201 for treatment of a subset of PGHD patients based on a once daily weight-based dosing regimen, the approval may include additional restrictions on the label that could make LUM-201 less attractive to physicians and patients compared to other products that may be approved for broader indications, which could limit potential sales of LUM-201.

If Lumos fails to obtain FDA or other regulatory approval of LUM-201 or if the approval is narrower than what it seeks, it could have a material adverse effect on Lumos' business, financial condition, results of operations and growth prospects.

Even if LUM-201 or any future product candidates receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payors and others in the medical community necessary for commercial success.

If LUM-201 or any future product candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, hospital administrators, patients, healthcare payors and others in the medical community. The degree of market acceptance of Lumos' product candidates, if approved for commercial sale, will depend on a number of factors, including the following:

- the prevalence and severity of any adverse events;
- their efficacy and potential advantages compared to alternative treatments;
- the price Lumos charges for its product candidates;
- the willingness of physicians to change their current treatment practices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support; and
- the availability of third-party coverage or adequate reimbursement.

For example, a number of companies offer therapies for treatment of PGHD patients based on a daily injection based regimen, and physicians, patients or their families may not be willing to change their current treatment practices in favor of LUM-201 even if it is able to eliminate daily injection dosing. If LUM-201 or any future product candidates, if approved, do not achieve an adequate level of acceptance, Lumos may not generate significant product revenue and it may not become profitable on a sustained basis or at all.

In addition, several companies, including large worldwide pharmaceutical companies are developing products that provide weekly injection-based treatment for PGHD. If one or more of such products are approved, physicians, patients and their families may prefer a once weekly treatment option over LUM-201's daily treatment.

LUM-201 has never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. Lumos is in the process of arranging for production of LUM-201 by a third-party manufacturer, which may not be successful, and this could delay regulatory approval and commercialization of LUM-201.

Lumos has an existing supply of the LUM-201 active pharmaceutical ingredient ("API") obtained in connection with the APA (as defined below) and the Lumos Merck Agreement (as defined below) that it believes will be sufficient for its Phase 2b Trial, subject to FDA review. The LUM-201 API has never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, and timely availability of raw materials. Even if Lumos could otherwise obtain regulatory approval for LUM-201, there is no assurance that any manufacturer it arranges will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If any manufacturer is unable to begin production in a timely and efficient manner or produce sufficient quantities of the approved product for commercialization, the commercialization efforts of Lumos would be impaired, which would have an adverse effect on its business, financial condition, results of operations and growth prospects.

Lumos' failure to successfully identify, acquire, develop and commercialize additional products or product candidates could impair its ability to grow.

Although a substantial amount of Lumos' efforts will focus on the continued clinical testing and potential approval of its product candidate, LUM-201, a key element of its long-term growth strategy is to acquire, develop, and/or market additional products and product candidates. Research programs to identify product candidates require

substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Because Lumos' internal research capabilities are limited, it may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to Lumos. The success of this strategy depends partly upon Lumos' ability to identify, select and acquire promising pharmaceutical product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with Lumos for the license or acquisition of product candidates and approved products. Lumos has limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into its current infrastructure. Moreover, Lumos may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or Lumos may fail to realize the anticipated benefits of such efforts. Any product candidate that Lumos acquires may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, Lumos cannot provide assurance that any products that it develops or approved products that it acquires will be manufactured profitably or achieve market acceptance.

Lumos currently has no sales or distribution personnel and only limited marketing capabilities. If Lumos is unable to develop a sales and marketing and distribution capability on its own or through collaborations or other marketing partners, it will not be successful in commercializing LUM-201 or other future products.

Lumos does not have sales or marketing infrastructure and has no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for any approved product, Lumos must either develop a sales and marketing organization or outsource these functions to third parties. If LUM-201 is approved, Lumos currently initially intends to commercialize it with its own specialty sales force in the United States, the European Union, and potentially other geographies.

There are risks involved with both establishing Lumos' own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which Lumos recruits a sales force and establishes marketing capabilities is delayed or does not occur for any reason, Lumos would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and Lumos' investment would be lost if it cannot retain or reposition its sales and marketing personnel.

Lumos also may not be successful entering into arrangements with third parties to sell and market its product candidates or may be unable to do so on terms that are favorable to it. Lumos likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market Lumos' products effectively and could damage Lumos' reputation. If Lumos does not establish sales and marketing capabilities successfully, either on its own or in collaboration with third parties, it will not be successful in commercializing its product candidates.

Lumos faces substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than it does.

The development and commercialization of new therapeutic products is highly competitive. Lumos faces competition with respect to LUM-201 and will face competition with respect to any product candidates that it may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market and sell rhGH therapies to Lumos' target patient group. These companies typically have a greater ability to reduce prices for their competing drugs to gain or retain market share and undermine the value proposition that Lumos might otherwise be able to offer to payors. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization, as well as manufacturers and sellers of the LUM-201 compound that may sell the compound illegally or for other indications. Many of these competitors are attempting to develop therapeutics for Lumos' target indications.

Lumos is developing its sole product candidate, LUM-201, for treatment of a subset of PGHD patients based on a once daily weight-based oral dosing regimen. The current standard of care for growth therapies for patients in the United States is a daily subcutaneous injection of rhGH. There are a variety of currently marketed daily rhGH therapies administered by daily subcutaneous injection and used for the treatment of Growth Hormone Deficiency ("GHD"), principally Norditropin® (Novo Nordisk A/S ("Novo Nordisk")), Humatrope® (Eli Lilly and Company ("Eli Lilly")), Nutropin-AQ® (F. Hoffman-La Roche Ltd./Genentech, Inc.), Genotropin® (Pfizer Inc.), Saizen® (Merck Serono S.A.), Tev-tropin® (Teva Pharmaceuticals Industries Ltd.), Omnitrope® (Sandoz GmbH), Valtropin® (LG Life Science and Biopartners GmbH), and Zomacton® (Ferring Pharmaceuticals, Inc.). These rhGH drugs, apart from Valtropin, are well-established therapies and are widely accepted by physicians, patients, caregivers, third-party payors and pharmacy benefit managers ("PBMs"), as the standard of care for the treatment of GHD. Physicians, patients, third-party payors and PBMs may not accept the addition of LUM-201 to their current treatment regimens for a variety of potential reasons, including concerns about incurring potential additional costs related to LUM-201, the perception that the use of LUM-201 will be of limited additional benefit to patients, or limited long-term safety data compared to currently available rhGH treatments.

In addition to the currently approved and marketed daily rhGH therapies, there are a variety of experimental therapies and devices that are in various stages of clinical development by companies already participating in the rhGH market as well as potential new entrants, principally Ascendis Pharma A/S ("Ascendis"), Novo Nordisk, Genexine Inc. ("Genexine") and OPKO Health, Inc. ("OPKO") (in collaboration with Pfizer).

Many of Lumos' competitors, including a number of large pharmaceutical companies that compete directly with it, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than Lumos does. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of Lumos' competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with Lumos in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, Lumos' programs.

Lumos may form strategic alliances in the future, and it may not realize the benefits of such alliances.

Lumos may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that it believes will complement or augment its business. These relationships or those like them may require Lumos to incur non-recurring and other charges, increase its near- and long-term expenditures, issue securities that dilute its existing stockholders or disrupt its management and business. In addition, Lumos faces significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, Lumos may not be successful in its efforts to establish a strategic partnership or other alternative arrangements for LUM-201 or any future product candidates and programs because its research and development pipeline may be insufficient, its product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view its product candidates and programs as having the requisite potential to demonstrate safety and efficacy. If Lumos licenses products or businesses, it may not be able to realize the benefit of such transactions if it is unable to successfully integrate them with its existing operations and company culture. Lumos cannot be certain that, following a strategic transaction or license, it will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to Lumos' product candidates could also delay the development and commercialization of its product candidates and reduce their competitiveness even if they reach the market.

If Lumos is able to commercialize LUM-201 or any future product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming Lumos' business.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, Lumos might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay its commercial launch of the product and

negatively impact the revenue it is able to generate from the sale of the product in that country. Adverse pricing limitations may hinder Lumos' ability to recoup its investment in one or more product candidates, even if its product candidates obtain regulatory approval.

Lumos' ability to commercialize LUM-201 or any future products successfully also will depend on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Lumos cannot be sure that reimbursement will be available for any product that it commercializes and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which Lumos obtains marketing approval. Obtaining reimbursement for Lumos' products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, Lumos may not be able to successfully commercialize any product candidate that it successfully develops.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers Lumos' costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover Lumos' costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Lumos' inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for new products that it develops could have a material adverse effect on its operating results, its ability to raise capital needed to commercialize products and its overall financial condition. In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take nine to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, Lumos may be required to conduct a clinical trial that compares the cost-effectiveness of its product to other available therapies. Lumos' business could be materially harmed if reimbursement of its approved products, if any, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels.

Product liability lawsuits against Lumos could cause it to incur substantial liabilities and to limit commercialization of any products that it may develop.

Lumos faces an inherent risk of product liability exposure related to the testing of LUM-201 and any future product candidates in human clinical trials and will face an even greater risk if it commercially sells any products that it may develop. If Lumos cannot successfully defend itself against claims that its product candidates or products caused injuries, it will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that Lumos may develop;
- injury to Lumos' reputation and significant negative media attention;
- withdrawal of patients from clinical trials or cancellation of trials;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue; and
- the inability to commercialize any products that Lumos may develop.

Any product liability insurance coverage Lumos may obtain in the future may not be adequate to cover all liabilities that it may incur. Insurance coverage is increasingly expensive. Lumos may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Lumos has agreed not to develop or seek to commercialize any products in the dermatological field, or the fields of Parkinson's, Huntington's and ALS diseases.

Pursuant to the terms of Lumos' settlement agreement with The Avicena Group, Inc. and its Chief Executive Officer, Lumos has agreed not to, among other things, develop, commercialize, market, sell, license, transfer or otherwise exploit any substance, therapeutic, diagnostic or other methodology in the dermatological field or the fields of Parkinson's, Huntington's and ALS diseases for a period of 25 years, beginning on November 19, 2012. As a result, Lumos may be limited in its ability to develop or collaborate on products in those fields, and Lumos could miss valuable future opportunities thus potentially adversely affecting Lumos' financial results, business and business prospects.

Risks Related to the Operation of Lumos' Business

Lumos' future success depends on its ability to retain its chief executive officer and other key members of its management team and to attract, retain and motivate qualified personnel.

Lumos is highly dependent on its chief executive officer and the other members of its management team. Under the terms of their employment, Lumos' executives may terminate their employment with Lumos at any time. The loss of the services of any of these people could impede the achievement of Lumos' research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to Lumos' success. Lumos may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Lumos also experiences competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, Lumos relies on consultants and advisors, including scientific and clinical advisors, to assist it in formulating its research and development and commercialization strategy. Lumos' consultants and advisors may be employed by employers other than Lumos and may have commitments under consulting or advisory contracts with other entities that may limit their availability to Lumos.

Lumos expects to expand its development, regulatory and sales and marketing capabilities, and as a result, Lumos may encounter difficulties in managing its growth, which could disrupt its operations.

As of September 30, 2019, Lumos had seven employees. Over the next several years, Lumos expects to experience significant growth in the number of its employees and the scope of its operations, particularly in the areas of drug development, regulatory affairs, commercial development and sales and marketing. To manage Lumos' anticipated future growth, it must continue to implement and improve its managerial, operational and financial systems, expand its facilities and continue to recruit and train additional qualified personnel. Lumos may not be able to effectively manage the expansion of its operations or recruit and train additional qualified personnel. The physical expansion of Lumos' operations may lead to significant costs and may divert its management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

- managing its clinical trials effectively, which it anticipates being conducted at numerous clinical sites;
- identifying, recruiting, maintaining, motivating and integrating additional employees with the expertise and experience Lumos will require;
- managing its internal development efforts effectively while complying with its contractual obligations to licensors, licensees, contractors and other third parties;
- managing additional relationships with various strategic partners, suppliers and other third parties;
- improving its managerial, development, operational and finance reporting systems and procedures; and
- expanding its facilities.

Lumos' failure to accomplish any of these tasks could prevent it from successfully growing. Any inability to manage growth could delay the execution of Lumos' business plans or disrupt its operations.

Business disruptions could seriously harm Lumos' future revenue and financial condition and increase its costs and expenses.

Lumos' operations could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm Lumos' operations and financial condition and increase its costs and expenses.

If Lumos obtains approval to commercialize LUM-201 outside the United States, it will be subject to additional risks.

If Lumos obtains approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect its business, including:

- different regulatory requirements for drug approvals and pricing and reimbursement regimes in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- potential liability under the U.S. Foreign Corrupt Practices Act ("FCPA") or comparable foreign regulations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Lumos' internal computer systems, or those of its contract research organizations ("CROs") or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of its drug development programs.

Despite the implementation of security measures, Lumos' internal computer systems and those of its CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While Lumos has not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in its operations, it could result in a material disruption of its drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in Lumos' regulatory approval efforts and significantly increase its costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to Lumos' data or applications, or inappropriate disclosure of confidential or proprietary information, Lumos could incur liability and the further development of any product candidates could be delayed.

Lumos' employees, independent contractors and consultants, principal investigators, CROs, contract manufacturing organizations ("CMOs") and other vendors, and any future commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for Lumos and harm its reputation.

Lumos is exposed to the risk that its employees, independent contractors and consultants, principal investigators, CROs, CMOs and other vendors, and any future commercial partners may engage in fraudulent conduct or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with manufacturing standards required by cGMP or Lumos' standards, to comply with federal

and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, and to report financial information or data accurately or disclose unauthorized activities to them. The misconduct of its employees and other Lumos service providers could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to Lumos' reputation. Lumos intends to adopt a code of business ethics and conduct, but it is not always possible to identify and deter such misconduct, and the precautions Lumos takes to detect and prevent this activity, such as the implementation of a quality system which entails vendor audits by quality experts, may not be effective in controlling unknown or unmanaged risks or losses or in protecting Lumos from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against them, and Lumos is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business and results of operations, including the imposition of significant fines or other sanctions. For example, if one of Lumos' manufacturing partners was placed under a consent decree, Lumos may be hampered in its ability to manufacture clinical or commercial supplies.

If Lumos fails to fulfill its obligations under its contractual commitments, its counterparties could terminate the applicable agreements or make claims against Lumos, which could have a materially adverse effect on Lumos.

Under Lumos' license agreement with Merck and its Asset Purchase Agreement (the "APA") with Ammonett Pharma LLC ("Ammonett"), Lumos is obligated to use commercially reasonable and diligent efforts to develop and commercialize LUM-201. Lumos is also obligated to make substantial milestone payments and royalties to both Merck and Ammonett, which may limit the future profitability of Lumos and the ability of Lumos to enter into marketing partnership agreements. If Lumos fails to fulfill its obligations under its contractual commitments to Merck, Ammonett, or any other counterparty, the counterparties could terminate the exclusive, worldwide license and collaboration agreement entered into in November 2014 (the "Lumos Merck Agreement") with or make claims against Lumos under both agreements, which could have a materially adverse effect on Lumos' business, results of operations and prospects.

Lumos relies on third parties to conduct its clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

Lumos does not independently conduct clinical trials. Lumos relies on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Lumos' reliance on these third parties for clinical development activities reduces its control over these activities but does not relieve it of its responsibilities. Lumos remains responsible for ensuring that each of its clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires Lumos to comply with standards, commonly referred to as good clinical practices ("GCP"), for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical trials are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be Lumos' competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct Lumos' clinical trials in accordance with regulatory requirements or Lumos' stated protocols, Lumos will not be able to obtain, or may be delayed in obtaining, regulatory approvals for its product candidates and will not be able to, or may be delayed in its efforts to, successfully commercialize its product candidates.

Lumos also relies on other third parties to store and distribute supplies for its clinical trials. Any performance failure on the part of Lumos' existing or future distributors could delay clinical development or regulatory approval of its product candidates or commercialization of its products, producing additional losses and depriving Lumos of potential product revenue.

Lumos currently relies and may continue to rely on a single third-party CMO to manufacture and supply LUM-201. If Lumos' manufacturer and supplier fails to perform adequately or fulfill its needs, Lumos may be required to incur significant costs and devote significant efforts to find a new supplier or manufacturer. Lumos may also face delays in the development and commercialization of its product candidates.

Lumos currently has limited experience in, and it does not own facilities for, clinical-scale manufacturing of its sole product candidate, LUM-201, and it currently relies and may continue to rely upon a single third-party CMO to manufacture and supply drug product for its clinical trials of LUM-201. The manufacture of pharmaceutical products in compliance with the FDA's cGMP requires significant expertise and capital investment, including the

development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements and foreign regulations. If any manufacturer contracted by Lumos were to encounter any of these difficulties or otherwise fail to comply with its obligations to Lumos or under applicable regulations, Lumos' ability to provide study drugs in its clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of Lumos' clinical trials, increase the costs associated with maintaining its clinical trial programs and, depending upon the period of delay, require Lumos to commence new trials at significant additional expense or terminate the trials completely.

All manufacturers of Lumos' product candidates must comply with cGMP requirements enforced by the FDA through Lumos' facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of Lumos' product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. Lumos has little control over its manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in clinical trial and product approval, product seizure or recall or withdrawal of product approval. If the safety of any product supplied is compromised due to Lumos' manufacturers' failure to adhere to applicable laws or for other reasons, Lumos may not be able to obtain regulatory approval for or successfully commercialize its products and it may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of Lumos' product candidates, entail higher costs or impair its reputation.

The number of third-party manufacturers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on Lumos' business. New manufacturers of any product candidate would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product candidate. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to Lumos.

Any future collaboration agreements Lumos may enter into for LUM-201 or any other product candidate may place the development of LUM-201 or other product candidates outside Lumos' control, may require Lumos to relinquish important rights or may otherwise be on terms unfavorable to Lumos.

Lumos may enter into collaboration agreements with third parties with respect to LUM-201 for the commercialization of this candidate in or outside the United States, or with respect to future product candidates for commercialization in or outside the United States. Lumos' likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Lumos will have limited control over the amount and timing of resources that its collaborators dedicate to the development or commercialization of its product candidates. Lumos' ability to generate revenue from these arrangements will depend on its collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving Lumos' product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to any such collaborations;
- collaborators may not pursue development and commercialization of Lumos' product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Lumos' products or product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend Lumos' intellectual property rights or may use its intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate its intellectual property or proprietary information or expose Lumos to potential liability;
- disputes may arise between Lumos and a collaborator, including related to Lumos' loss of licensing rights it might have sublicensed to collaborators, that causes the delay or termination of the research, development or commercialization of Lumos' product candidates or that results in costly litigation or arbitration that diverts management's attention and resources;
- Lumos' right to sublicense patent and other rights to third party collaborators is subject to obtaining the prior written consent of Lumos' licensor for sublicenses in the United States, major European countries and Japan (such consent not to be unreasonably withheld);
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering Lumos' products that results from Lumos' collaborating with them, and in such cases, Lumos would not have the exclusive right to commercialize such intellectual property.

Any termination or disruption of collaborations could result in delays in the development of product candidates, increases in Lumos' costs to develop the product candidates or the termination of development of a product candidate.

Risks Related to Lumos' Intellectual Property

Lumos' ability to successfully commercialize its technology and products may be materially adversely affected if it is unable to obtain and maintain effective intellectual property rights for its technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad.

Lumos' success depends on its ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to its proprietary technology and products.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of the patent rights Lumos relies on are highly uncertain. Pending and future patent applications may not result in patents being issued which protect Lumos' technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the patents Lumos relies on or narrow the scope of Lumos' patent protection. The laws of foreign countries may not protect Lumos' rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, Lumos cannot be certain that the inventors of the key patents Lumos has acquired with respect to LUM-201 were the first to make the inventions claimed in Lumos' licensed patents or pending patent applications, or that Lumos was the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent.

Even if the pending patent applications Lumos relies on issue as patents, they may not issue in a form that will provide Lumos with any meaningful protection, prevent competitors from competing with Lumos or otherwise

provide it with any competitive advantage. Lumos' competitors may be able to circumvent its patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the patents Lumos relies on may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit Lumos' ability to stop or prevent others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of Lumos' technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, Lumos' patent portfolio may not provide it with sufficient rights to exclude others from commercializing products similar or identical to Lumos' or otherwise provide it with a competitive advantage.

Lumos does not have composition of matter patent protection with respect to LUM-201.

Lumos owns certain patents and patent applications with claims directed to specific methods of using LUM-201 and it may obtain marketing exclusivity from the FDA and the EMA for a period of seven and a half and 12 years, respectively, because LUM-201 has not been approved in these markets and has received Orphan Drug Designation ("ODD") for treatment of GHD. However, Lumos does not have composition of matter protection in the United States and elsewhere covering LUM-201. Since Lumos does not have a composition of matter patent on LUM-201 and the chemical structure of LUM-201 is in the public domain, it is possible for another company to develop LUM-201 for another indication and market the drug for indications where Lumos does not have granted methods of treatment claims or, if approved by the FDA and EMA for its orphan-designated indications, market exclusivity. If LUM-201 is approved, Lumos may be limited in its ability to list its patents in the FDA's Orange Book if the use of its product, consistent with its FDA-approved label, would not fall within the scope of Lumos' patent claims. Also, Lumos' competitors may be able to offer and sell products so long as these competitors do not infringe any other patents that Lumos (or third parties) hold, including patents with claims for method of use patents. In general, method of use patents are more difficult to enforce than composition of matter patents because, for example, of the risks that the FDA may approve alternative uses of the subject compounds not covered by the method of use patents, and others may engage in off-label sale or use of the subject compounds. Physicians are permitted to prescribe an approved product for uses that are not described in the product's labeling. Although off-label prescriptions may infringe its method of use patents, the practice is common across medical specialties and such infringement is difficult to prevent or prosecute. FDA approval of uses that are not covered by Lumos' patents would limit Lumos' ability to generate revenue from the sale of LUM-201, if approved for commercial sale.

Lumos may become involved in legal proceedings to protect or enforce its intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe or otherwise violate the patents Lumos relies on, or Lumos' other intellectual property rights. To counter infringement or unauthorized use, Lumos may be required to file infringement claims, which can be expensive and time-consuming. Any claims that Lumos asserts against perceived infringers could also provoke these parties to assert counterclaims against it alleging that it infringed their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent Lumos is asserting is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patents Lumos is asserting do not cover the technology in question. An adverse result in any litigation proceeding could put one or more patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of Lumos' confidential information could be compromised by disclosure during this type of litigation.

Interference or derivation proceedings provoked by third parties or brought by the United States Patent and Trademark Office (the "USPTO") or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to patents and patent applications. Lumos or its licensers may become involved in proceedings, including oppositions, interferences, derivation proceedings inter partes reviews, patent nullification proceedings, or re-examinations, challenging its patent rights or the patent rights of others, and the outcome of any such proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, important patent rights, allow third parties to commercialize Lumos' technology or products and compete directly with it, without payment to it, or result in its inability to manufacture or commercialize products without infringing third-party patent rights. Lumos' business could be harmed if the prevailing party does not offer it a license on commercially reasonable terms, if any license is offered at all. Litigation

or other proceedings may fail and, even if successful, may result in substantial costs and distract Lumos' management and other employees. Lumos may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, data which form the basis of Lumos' key patent and patent applications were the result of certain clinical trials conducted by Merck, and disagreements may therefore arise as to the ownership or validity of any intellectual property developed pursuant to such relationship. If Lumos is unable to resolve these disputes, it could lose valuable intellectual property rights.

Even if resolved in Lumos' favor, litigation or other legal proceedings relating to intellectual property claims may cause Lumos to incur significant expenses and could distract its technical and/or management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of Lumos' common stock. Such litigation or proceedings could substantially increase Lumos' operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could have a material adverse effect on Lumos' ability to compete in the marketplace.

Third parties may initiate legal proceedings alleging that Lumos is infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of Lumos' business.

Lumos' commercial success depends upon its ability and the ability of its collaborators to develop, manufacture, market and sell its product candidates and use its proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. Lumos may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to its products and technology. Third parties may assert infringement claims against Lumos based on existing or future intellectual property rights. If Lumos is found to infringe a third-party's intellectual property rights, Lumos could be required to obtain a license from such third-party to continue developing and marketing Lumos' products and technology. Lumos may also elect to enter into such a license in order to settle pending or threatened litigation. However, Lumos may not be able to obtain any required license on commercially reasonable terms or at all. Even if Lumos was able to obtain a license, it could be non-exclusive, thereby giving Lumos' competitors access to the same technologies licensed to Lumos, and could require Lumos to pay significant royalties and other fees. Lumos could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, Lumos could be found liable for monetary damages. A finding of infringement could prevent Lumos from commercializing its product candidates or force it to cease some of its business operations, which could materially harm its business. Certain Lumos employees and consultants were previously employed at universities or other biotechnology or pharmaceutical companies, including its competitors or potential competitors. Although Lumos tries to ensure that its employees do not use the proprietary information or know-how of others in their work for Lumos, Lumos may be subject to claims that it or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. These and other claims that Lumos has misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on its business to the infringement claims discussed above.

Even if Lumos is successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause Lumos to incur significant expenses, and could distract its technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of Lumos' common stock. Such litigation or proceedings could substantially increase Lumos' operating losses and reduce its resources available for development activities. Lumos may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of Lumos' competitors may be able to sustain the costs of such litigation or proceedings more effectively than Lumos can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could have a material adverse effect on Lumos' ability to compete in the marketplace.

If Lumos is unable to protect the confidentiality of its trade secrets, the value of its technology could be materially adversely affected, harming its business and competitive position.

In addition to Lumos' products and patented technology, it relies upon confidential proprietary information, including trade secrets, unpatented know-how, technology and other proprietary information, to develop and maintain its competitive position. Any disclosure to or misappropriation by third parties of Lumos' confidential proprietary

information could enable competitors to quickly duplicate or surpass its technological achievements, thus eroding its competitive position in the market. Lumos seeks to protect its confidential proprietary information, in part, by confidentiality agreements with its employees and its collaborators and consultants. Lumos also has agreements with its employees and selected consultants that obligate them to assign their inventions to Lumos. These agreements are designed to protect Lumos' proprietary information; however, Lumos cannot be certain that its trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to its trade secrets, or that technology relevant to its business will not be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, Lumos may not have adequate remedies for any such breach or violation, and Lumos could lose its trade secrets through such breaches or violations. Further, Lumos' trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by its competitors. In addition, intellectual property laws in foreign countries may not protect trade secrets and confidential information to the same extent as the laws of the United States. If Lumos is unable to prevent disclosure of the intellectual property related to its technologies to third parties, it may not be able to establish or maintain a competitive advantage in its market, which would harm its ability to protect its rights and have a material adverse effect on its business.

Lumos may not be able to protect and/or enforce its intellectual property rights throughout the world.

Filing, prosecuting and defending the intellectual property rights of Lumos throughout the world may be prohibitively expensive to Lumos and to its licensors. Competitors may use Lumos' technologies in jurisdictions where Lumos or its licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where Lumos has patent protection but where enforcement is not as strong as in the United States. These products may compete with Lumos' products in jurisdictions where it or its licensors do not have any issued patents and its patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals and biopharmaceuticals, which could make it difficult for Lumos to stop the infringement of its patents or marketing of competing products in violation of its proprietary rights generally. Proceedings to enforce Lumos' patent rights in foreign jurisdictions could result in substantial cost and divert its efforts and attention from other aspects of its business.

Lumos is dependent on licensed intellectual property. If Lumos were to lose its rights to licensed intellectual property, Lumos would not be able to continue developing its sole product candidate, LUM-201. If Lumos breaches the agreement under which Lumos licenses the use, development and commercialization rights to its sole product candidate or technology from third parties or, in certain cases, Lumos fails to meet certain development or payment deadlines, Lumos could lose license rights that are important to its business.

In connection with the APA, Lumos was assigned the Lumos Merck Agreement under which Lumos is granted rights to intellectual properties that are important to its business, and Lumos may need to enter into additional license agreements in the future. Lumos' existing license agreement imposes, and Lumos expects that future license agreements will impose, various development, regulatory and/or commercial diligence obligations, payment of fees, milestones and/or royalties and other obligations. If Lumos fails to comply with its obligations under the agreement, Merck, the licensor, may have the right to terminate the license, in which event Lumos would not be able to develop or market products, which could be covered by the license. Lumos' business could suffer, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if Lumos is unable to enter into necessary licenses on acceptable terms.

As Lumos has done previously, Lumos may need to obtain licenses from third parties to advance its research or allow commercialization of sole product candidate, and Lumos cannot provide any assurances that third-party patents do not exist that might be enforced against LUM-201 or future products in the absence of such a license. Lumos may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if Lumos is able to obtain a license, it may be non-exclusive, thereby giving competitors access to the same technologies licensed to Lumos. In that event, Lumos may be required to expend significant time and resources to develop or license replacement technology. If Lumos is unable to do so, Lumos may be unable to develop or commercialize the affected product candidates, which could materially harm Lumos' business and the third parties owning such intellectual property rights could seek either an injunction prohibiting Lumos' sales, or, with respect to Lumos' sales, an obligation to pay royalties and/or other forms of compensation.

Licensing of intellectual property is of critical importance to Lumos' business and involves complex legal, business and scientific issues. Disputes may arise between Lumos and its licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which Lumos' technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- Lumos' right to sublicense patent and other rights to third parties under collaborative development relationships;
- Lumos' diligence obligations with respect to the use of the licensed technology in relation to development and commercialization of Lumos' product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by Lumos' licensors and Lumos and Lumos' partners.

If disputes over intellectual property that Lumos has licensed prevent or impair Lumos' ability to maintain Lumos' current licensing arrangements on acceptable terms, Lumos may be unable to successfully develop and commercialize the affected product candidates. Lumos may enter into additional license(s) to third-party intellectual property that are necessary or useful to Lumos' business.

Lumos' current license for LUM-201 and any future licenses that Lumos may enter into impose various royalty payments, milestone, and other obligations. For example, the licensor may retain control over patent prosecution and maintenance under a license agreement, in which case, Lumos may not be able to adequately influence patent prosecution or prevent inadvertent lapses of coverage due to failure to pay maintenance fees. If Lumos fails to comply with any of its obligations under a current or future license agreement, Lumos' licensor(s) may allege that Lumos has breached Lumos' license agreement and may accordingly seek to terminate the license. In addition, future licensor(s) may decide to terminate Lumos' license at will. Termination of any current or future licenses could result in Lumos' loss of the right to use the licensed intellectual property, which could materially adversely affect Lumos' ability to develop and commercialize a product candidate or product, if approved, as well as harm Lumos' competitive business position and business prospects.

Intellectual property rights do not necessarily address all potential threats to Lumos' competitive advantage.

The degree of future protection afforded by Lumos' intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect Lumos' business or permit it to maintain its competitive advantage. The following examples are illustrative:

- others may be able to make and/or use products that are similar to Lumos' product candidates but that are not covered by the claims of the patents that Lumos owns;
- inventors of patents that Lumos owns might not have been the first to make the inventions covered by an issued patent or pending patent application and/or might not have been the first to file patent applications covering an invention;
- others may independently develop similar or alternative technologies or duplicate any of Lumos' or its licensors' technologies without infringing its intellectual property rights;
- pending patent applications may not lead to issued patents, including in the key market of China;
- issued patents may not provide Lumos with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by Lumos' competitors;
- Lumos' competitors might conduct research and development activities in countries where Lumos does not have patent rights and then use the information learned from such activities to develop competitive products for sale in its major commercial markets;
- Lumos may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on Lumos' business.

Should any of these events occur, they could significantly harm Lumos' business, results of operations and prospects.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and Lumos' or its licensors' patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid by Lumos and/or its licensors to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the licensed patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, Lumos' competitors might be able to use Lumos' technologies and those technologies licensed to it and this circumstance would have a material adverse effect on Lumos' business.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of Lumos' issued patents.

In March 2013, under the America Invents Act (the "AIA"), the United States moved to a first-to-file system and made certain other changes to its patent laws. The full extent of these changes are still not completely clear as, for example, the courts have yet to address many of the provisions of the AIA. Thus, the applicability of the act and new regulations on specific patents and patent applications discussed herein have not been determined and would need to be reviewed. Accordingly, it is not yet clear what, if any, impact the AIA will have on the operation of Lumos' business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, all of which could have a material adverse effect on Lumos' business and financial condition.

If Lumos is unable to obtain a patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of its marketing exclusivity for its product candidates, its business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of Lumos' product candidates, if any, one or more of the United States patents covering its approved product(s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of Lumos' product candidates. Nevertheless, Lumos may not be granted patent term extension either in the United States or in any foreign country because of, for example, it or its licensors failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable statutory requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than Lumos requests.

If Lumos is unable to obtain patent term extension or restoration, or the term of any such extension is less than requested, the period during which Lumos will have the right to exclusively market its product will be shortened and its competitors may obtain approval of competing products following its patent expiration, and Lumos' revenue could be reduced, possibly materially.

Risks Related to Government Regulation of Lumos

The regulatory approval process is expensive, time consuming and uncertain and may prevent Lumos or its collaboration partners from obtaining approvals for the commercialization of its product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither Lumos nor its collaboration partners are permitted to market Lumos' product candidates in the United States until Lumos receives approval of an NDA from

the FDA. Neither Lumos nor its collaboration partners have submitted an application or received marketing approval for LUM-201 or any future product candidates. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with the FDA and other applicable United States and foreign regulatory requirements may subject Lumos to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs filed by Lumos;
- restrictions on operations, including costly new manufacturing requirements; and
- seizure or detention of Lumos' products or import bans.

Prior to receiving approval to commercialize any of Lumos' product candidates in the United States or abroad, Lumos and its collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if Lumos and its collaboration partners believe the preclinical or clinical data for its product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of Lumos' product candidates to humans may produce undesirable adverse events, which could interrupt, delay or cause suspension of clinical trials of Lumos' product candidates and result in the FDA or other regulatory authorities denying approval of its product candidates for any or all targeted indications.

Regulatory approval of an NDA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and Lumos could encounter problems that cause it to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to, the following:

- a product candidate may not be deemed safe or effective, only moderately effective or have undesirable or unintended adverse events, toxicities or other characteristics that preclude Lumos' obtaining marketing approval or prevent or limit commercial use;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient, or may disagree with Lumos' interpretation of data from preclinical studies or clinical trials;
- the FDA might not approve Lumos' or its third-party manufacturer's processes or facilities;
- the FDA may disagree with the design, implementation or results of Lumos' clinical trials;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which Lumos seeks approval;
- data collected from clinical trials of Lumos' drug candidates may not be sufficient to support the submission of an NDA; and
- Lumos may be unable to demonstrate to the FDA a drug candidate's risk-benefit ratio for its proposed indication is acceptable.

If LUM-201 or any future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain regulatory approval, Lumos' business and results of operations will be materially and adversely harmed.

Even if Lumos receives regulatory approval for a product candidate, Lumos will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject it to penalties if it fails to comply with applicable regulatory requirements.

Once regulatory approval has been granted, the approved product and its manufacturer are subject to continual review by the FDA and/or non-U.S. regulatory authorities. Any regulatory approval that Lumos or any future collaboration partners receive for LUM-201 or any future product candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up trials to monitor the safety and efficacy of the product. In addition, if the FDA and/or non-U.S. regulatory authorities approve LUM-201 or any future product candidates, Lumos will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for its products.

Regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use, and if regulatory authorities believe that Lumos is in violation of these restrictions, Lumos may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act in the United States, and other comparable regulations in foreign jurisdictions, relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorney Generals and other foreign regulatory agencies alleging violations of United States federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in foreign jurisdictions.

In addition, manufacturers of Lumos' drug products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture Lumos' drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If Lumos or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or Lumos, including requiring withdrawal of the product from the market or suspension of manufacturing. If Lumos, its product candidates or the manufacturing facilities for its product candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, Lumos could be subject to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by it;
- restrictions on operations, including costly new manufacturing requirements; and
- seizure or detention of its products or import bans.

The regulatory requirements and policies may change and additional government regulations may be enacted with which Lumos may also be required to comply. Lumos cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If Lumos is not able to maintain regulatory compliance, it may not be permitted to market its future products and its business may suffer.

Failure to obtain regulatory approvals in foreign jurisdictions will prevent Lumos from marketing its products internationally.

Lumos intends to seek a distribution and marketing partner for LUM-201 outside the United States and may market future products in international markets. In order to market Lumos' future products in regions such as the European Economic Area (the "EEA"), Asia Pacific, and many other foreign jurisdictions, it must obtain separate regulatory approvals.

For example, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization (an "MA"). Before granting the MA, the EMA or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. In Japan, the Pharmaceuticals and Medical Devices Agency, of the Ministry of Health Labour and Welfare, must approve an application under the Pharmaceutical Affairs Act before a new drug product may be marketed in Japan.

Lumos has had limited interactions with foreign regulatory authorities. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Moreover, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. Lumos may not obtain foreign regulatory approvals on a timely basis, if at all. Lumos may not be able to file for regulatory approvals and even if it files it may not receive necessary approvals to commercialize its products in any market.

Healthcare reform measures could hinder or prevent Lumos' product candidates' commercial success.

In the United States, there have been and Lumos expects there will continue to be a number of legislative and regulatory changes to the healthcare system in ways that could affect its future revenue and profitability and the future revenue and profitability of its potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA"), was enacted in 2010. The PPACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The PPACA, among other things:

- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs";
- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%, effective 2011;
- could result in the imposition of injunctions;
- requires collection of rebates for drugs paid by Medicaid managed care organizations;
- requires manufacturers to participate in a coverage gap discount program, under which they now must agree to offer 70% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- creates a process for approval of biologic therapies that are similar or identical to approved biologics.

While the United States Supreme Court upheld the constitutionality of most elements of the PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. For example, on December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Although the Texas U.S. District Court Judge, as well as the presidential administration and the Centers for Medicare & Medicaid Services ("CMS") have stated that the ruling will have no immediate effect pending appeal of the decision. On

July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case. Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Lumos cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect its business and financial results and Lumos cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect its business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, which triggered the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the "ATRA"), which delayed for another two months the budget cuts mandated by the sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the two percent Medicare reductions went into effect. Lumos cannot predict whether any additional legislative changes will affect its business. There have been several recent Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. Lumos cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- Lumos' ability to set a price that it believes is fair for its products;
- Lumos' ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, changes in regulatory requirements and guidance may occur and Lumos may need to amend clinical trial protocols to reflect these changes. Amendments may require Lumos to resubmit its clinical trial protocols to institutional review boards ("IRBs") for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance and/or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and the drug approval process. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical trials before completion or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Given the serious public health risks of high-profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly REMS, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

Lumos' relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with its current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose Lumos to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings. If Lumos fails to comply with healthcare regulations, it could face substantial penalties and its business, operations and financial condition could be adversely affected.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which Lumos obtains marketing approval. Lumos' current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose Lumos to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which Lumos markets, sells and distributes its products for which it obtains marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following, without limitation, are:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like Lumos which provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal transparency requirements under the Sunshine Act requires manufacturers of drugs, devices, biologics and medical supplies to report to the CMS information related to certain payments and other transfers of value, including physician ownership and investment interests, made to physicians and teaching hospitals;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state laws require biotechnology companies to report information on the pricing of certain drug products, and certain state and local laws require the registration of pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the European Union is governed by the General Data Protection Regulation (the "GDPR"), which extends the

geographical scope of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. The GDPR may increase Lumos' responsibility and liability in relation to personal data that it processes, and it may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if Lumos' efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect its business in the European Union.

Efforts to ensure that Lumos' current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that Lumos' business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Lumos' operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of its operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if Lumos is successful in defending against any such actions that may be brought against it, its business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom Lumos expects to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to the Combined Company

If any of the events described in "Risks Related to the Reverse Stock Split," "Risks Related to NewLink," "Risks Related to Lumos' Financial Condition and Capital Requirements," "Risks Related to the Development and Commercialization of Lumos' Product Candidate," "Risks Related to the Operation of Lumos' Business," "Risks Related to Lumos' Intellectual Property" or "Risks Related to Government Regulation of Lumos" occur, those events could cause potential benefits of the Merger not to be realized.

Following completion of the Merger, the combined company will be susceptible to many of the risks described in "Risks Related to the Reverse Stock Split," "Risks Related to NewLink," "Risks Related to Lumos' Financial Condition and Capital Requirements," "Risks Related to the Development and Commercialization of Lumos' Product Candidate," "Risks Related to the Operation of Lumos' Business," "Risks Related to Lumos' Intellectual Property" and "Risks Related to Government Regulation of Lumos." To the extent any of the events in the risks described in those sections occur, those events could cause the potential benefits of the Merger not to be realized and the market price of the combined company's common stock to decline.

The historical financial information of NewLink and Lumos presented herein may not be representative of their respective results or financial condition if they had been operated as a combined company, and as a result may not be representative of the combined company's results or financial condition after the Merger.

The historical financial information of NewLink and Lumos included elsewhere in this proxy statement reflects assumptions and allocations made by NewLink and Lumos, respectively. The historical results and financial condition of NewLink and Lumos presented herein may be different from those that would have resulted had NewLink and Lumos been operated together as a combined company during the applicable periods or at the applicable dates. As a result, the historical financial information of NewLink and Lumos is not indicative of future operating results or financial position of the combined company.

The unaudited pro forma condensed combined financial information presented herein may not be representative of the combined companies' results after the Merger.

The unaudited pro forma condensed combined financial information included elsewhere in this proxy statement has been presented for informational purposes only and is not necessarily indicative of the financial position or results of operations that actually would have occurred had the Merger been completed as of the date indicated, nor is it indicative of future operating results or financial position. The unaudited pro forma condensed combined financial information has been derived from the historical financial statements of NewLink and Lumos and adjustments and assumptions have been made regarding the combined company after giving effect to the Merger. The information

upon which these adjustments and assumptions have been made is preliminary, and these kinds of adjustments and assumptions are difficult to make with accuracy. Moreover, the unaudited pro forma condensed combined financial information does not reflect all costs that are expected to be incurred by the combined company in connection with the Merger. The assumptions used in preparing the unaudited pro forma condensed combined financial information may not ultimately be accurate, and other factors may affect the combined company's results and financial condition following consummation of the Merger. The unaudited pro forma condensed combined financial information does not reflect the costs of integration activities or transaction-related costs or incremental expenditures associated with the Merger. Accordingly, the unaudited pro forma condensed combined financial information included elsewhere in this proxy statement does not reflect what NewLink's or Lumos' results or financial condition would have been had NewLink and Lumos been a consolidated entity during all periods presented.

NewLink and Lumos do not anticipate that the combined company will pay any cash dividends in the foreseeable future.

The current expectation is that the combined company will retain its future earnings, if any, to fund the development and growth of the combined company's business. As a result, capital appreciation, if any, of the common stock of the combined company will be your sole source of gain, if any, for the foreseeable future.

The combined company's business and operations would suffer in the event of system failures, security breaches or cyber-attacks.

The combined company's computer systems, as well as those of various third parties on which the combined company will rely, including CROs and other contractors, consultants, and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters, terrorism, war and telecommunication and electrical failures. Incompatibilities or difficulties with the integration of NewLink's and Lumos' computer systems following the closing of the Merger may exacerbate such effects. The combined company will rely on third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. The combined company may in the future experience material system failures or security breaches that could cause interruptions in the combined company's operations or result in a material disruption of the combined company's drug development programs. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in the combined company's regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to the data or applications of the combined company, or inappropriate disclosure of personal, confidential or proprietary information, the combined company could incur liability and the further development of its product candidates could be delayed.

Failure by the combined company upon completion of the Merger to comply with the initial listing standards of Nasdaq will prevent its stock from being listed on Nasdaq.

Upon completion of the Merger, we, under the new name "Lumos Pharma, Inc.," will be required to meet the initial listing requirements to maintain the listing and continued trading of our shares on Nasdaq. These initial listing requirements are more difficult to achieve than the continued listing requirements. Pursuant to the Merger Agreement, we agreed to use our commercially reasonable efforts to cause the shares of our common stock being issued in the Merger to be approved for listing on Nasdaq. Based on information currently available to us, we anticipate that our stock will be unable to meet the $4.00 minimum bid price initial listing requirement at the closing of the Merger unless we effect a reverse stock split. Pursuant to the Merger Agreement and subject to NewLink stockholder approval, the NewLink Board intends to effect a reverse stock split of the shares of our common stock at a ratio of between one-for-five to one-for-nine, with such specific ratio to be mutually agreed upon by us and Lumos. In addition, often times a reverse stock split will not result in a trading price for the affected common stock that is proportional to the ratio of the split. Following the Merger, if we are unable to satisfy Nasdaq listing requirements, Nasdaq may notify the combined company that our shares of common stock will not be listed on Nasdaq.

Upon a potential delisting from Nasdaq, if the combined company common stock is not then eligible for quotation on another market or exchange, trading of the shares could be conducted in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin

Board. In such event, it is likely that there would be significantly less liquidity in the trading of the combined company's common stock; decreases in institutional and other investor demand for the shares, coverage by securities analysts, market making activity and information available concerning trading prices and volume; and fewer broker dealers willing to execute trades in the combined company common stock. Also, it may be difficult for the combined company to raise additional capital if the combined company's common stock is not listed on a major exchange. The occurrence of any of these events could result in a further decline in the market price of the combined company's common stock and could have a material adverse effect on the combined company.

The Merger will result in changes to the NewLink Board and the combined company may pursue different strategies than either NewLink or Lumos may have pursued independently.

If NewLink and Lumos complete the Merger, the composition of the NewLink Board will change in accordance with the Merger Agreement. The combined company will be led by experienced senior management from both NewLink and Lumos and a board of directors of seven members with three designated by NewLink, three designated by Lumos, and one to be designated following the Merger by the board of directors of the combined company. Currently, it is anticipated that the combined company will initially continue to advance the product and development efforts and business strategies of Lumos. However, because the composition of the board of directors of the combined company will consist of directors from both NewLink and Lumos, the combined company may determine to pursue certain business strategies that neither NewLink nor Lumos would have pursued independently.

Future sales of shares by existing stockholders could cause the combined company's stock price to decline.

If existing NewLink stockholders and Lumos stockholders sell, or indicate an intention to sell, substantial amounts of the combined company's common stock in the public market after legal restrictions on resale discussed in this proxy statement lapse, the trading price of the common stock of the combined company could decline. Based on an assumed closing date of December 31, 2019, the combined company is expected to have outstanding a total of approximately 74.7 million shares of common stock (prior to giving effect to the proposed reverse stock split) immediately following the closing of the Merger. All of our and Lumos' executive officers and directors and certain principal stockholders are subject to lock-up agreements that restrict their ability to transfer shares of the combined company's capital stock during the period ending on, and including, the 180th day after the date of the closing of the Merger, subject to specified exceptions. After the lock-up agreements expire, approximately 42.4 million shares of common stock (prior to giving effect to the proposed reverse stock split) held by the combined company's directors, executive officers and principal stockholders will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended (the "Securities Act") and various vesting agreements.

In addition, at the Effective Time, outstanding options to purchase Lumos common stock will be assumed by NewLink and converted into options to purchase a number of shares of NewLink's common stock at the exchange ratio applicable to exchanging shares of Lumos common stock for NewLink's common stock ("Common Stock Exchange Ratio"). NewLink expects to assume outstanding Lumos options to acquire approximately 2.0 million shares of common stock (on an as-converted to NewLink's common stock basis and prior to giving effect to the proposed reverse stock split). The combined company intends to register all of the shares of common stock issuable upon exercise of outstanding Lumos options, and upon the exercise of any options or other equity incentives the combined company may grant in the future, for public resale under the Securities Act. Accordingly, these shares will be able to be freely sold in the public market upon issuance as permitted by any applicable vesting requirements, subject to the lock-up agreements described above and Rule 144 to the extent applicable.

The combined company's management will be required to devote substantial time to comply with public company regulations.

As a public company, the combined company will incur significant legal, accounting and other expenses that Lumos did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act as well as rules implemented by the SEC and Nasdaq, impose various requirements on public companies, including those related to corporate governance practices. The combined company's management and other personnel will need to devote a substantial amount of time to these requirements. In addition, there has been a significant reduction in staff of NewLink in recent years that has left fewer personnel available to devote time to these requirements. Certain members of Lumos' management, who will continue as a part of the management team of the combined company, do not have significant experience in addressing these requirements. Moreover, these rules and regulations will increase the combined company's legal and financial compliance costs relative to those of Lumos and will make some activities more time consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that the combined company maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, the combined company must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The combined company's compliance with these requirements will require that it incur substantial accounting and related expenses and expend significant management efforts. The combined company may need to hire additional accounting and financial staff to satisfy the ongoing requirements of Section 404 of the Sarbanes-Oxley Act. The costs of hiring such staff may be material and there can be no assurance that such staff will be immediately available to the combined company. Moreover, if the combined company is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if the combined company or its independent registered public accounting firm identifies deficiencies in its internal control over financial reporting that are deemed to be material weaknesses, investors could lose confidence in the accuracy and completeness of the combined company's financial reports, the market price of the combined company's common stock could decline and the combined company could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

The sale or availability for sale of a substantial number of shares of common stock of the combined company after the Merger and after expiration of the lock-up period could adversely affect the market price of such shares after the Merger.

Sales of a substantial number of shares of common stock of the combined company in the public market after the Merger or after expiration of the lock-up period and other legal restrictions on resale, or the perception that these sales could occur, could adversely affect the market price of such shares and could materially impair the combined company's ability to raise capital through equity offerings in the future.

NewLink is unable to predict what effect, if any, market sales of securities held by significant stockholders, directors or officers of the combined company or the availability of these securities for future sale will have on the market price of the combined company's common stock after the Merger.

Some provisions of the combined company's charter documents and Delaware law may have antitakeover effects that could discourage an acquisition of the combined company by others, even if an acquisition would be beneficial to the combined company's stockholders, and may prevent attempts by the combined company's stockholders to replace or remove the combined company's management.

Provisions in the combined company's amended and restated certificate of incorporation and amended and restated bylaws as well as provisions of the Delaware General Corporation Law ("DGCL") could make it more difficult for a third party to acquire the combined company or increase the cost of acquiring the combined company, even if doing so would benefit stockholders, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

- establishing a classified board of directors such that not all members of the board are elected at one time;
- allowing the authorized number of the combined company's directors to be changed only by resolution of the board of directors;
- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by the combined company stockholders to replace or remove management by making it more difficult for stockholders to replace members of the combined company's board of directors, which will be responsible for appointing the members of the combined company's management. In addition, the combined company will be subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by the board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to the combined company stockholders.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This proxy statement and the documents to which we refer you to in this proxy statement include certain "forward-looking statements" within the meaning of, and subject to the safe harbor created by, Section 27A of the Securities Act, Section 21E of the Exchange Act and the Private Securities Litigation Reform Act of 1995, which are referred to as the safe harbor provisions with respect to the businesses, strategies and plans of us, our expectations relating to the Merger and the combined company's future financial condition and performance. Statements included in or incorporated by reference into this proxy statement that are not historical facts are forward-looking statements, including statements about the beliefs and expectations of the management of each of NewLink and Lumos. Words such as "believe," "continue," "could," "expect," "anticipate," "intends," "estimate," "forecast," "project," "should," "may," "will," "would" or the negative thereof and similar expressions are intended to identify such forward-looking statements that are intended to be covered by the safe harbor provisions.

We caution investors that any forward-looking statements are subject to known and unknown risks and uncertainties, many of which are outside our control, and which may cause actual results and future trends to differ materially from those matters expressed in, or implied or projected by, such forward-looking statements, which speak only as of the date of this proxy statement. Investors are cautioned not to place undue reliance on these forward-looking statements.

These forward-looking statements include, among others, results of clinical trials for product candidates; timing of release of data from ongoing clinical trials; plans related to execution of clinical trials; plans related to moving additional indications into clinical development; the expected focus of the combined company; the development plan for LUM-201; the development plan for NewLink's existing pipeline; potential partnership and out-licensing opportunities; the timing of and the ability to obtain and maintain regulatory approvals for product candidates; the clinical utility of the existing and future product candidates; the intellectual property position; the potential benefits of strategic collaboration agreements and the ability to enter into strategic arrangements; plans and expectations related to continued listing on Nasdaq; NewLink's, Lumos' or the combined company's future financial performance, the impact of management changes, organizational restructuring, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; expectations regarding the composition of the board of directors and management, capitalization, resources and ownership structure of the combined company; expectations regarding the sufficiency of the combined company's resources to fund the advancement of any development program or the completion of any clinical trial; the potential benefits of the Merger; the expected completion and timing of the Merger and other information relating to the Merger; expected costs associated with termination benefits and financial impact of the reduction in force; the potential timing and impact of the proposed reverse stock split; and any other statements other than statements of historical fact.

Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink or Lumos makes due to a number of important factors, including:

- the risk that the Merger may not be completed in a timely manner or at all, which may adversely affect NewLink's business and the price of the common stock of NewLink;
- the failure to satisfy any of the conditions to the consummation of the Merger, including approval of the issuance of shares of NewLink's common stock in the Merger and the resulting "change of control" of NewLink under Nasdaq rules or the contemplated reverse stock split;
- the occurrence of any event, change or other circumstance that could give rise to the termination of the Merger Agreement;
- the risk that the Merger Agreement may be terminated in circumstances that require NewLink to pay a termination fee to Lumos;
- risks related to the ability to realize the anticipated benefits of the Merger, including the risk that the businesses will not be integrated successfully;
- the effect of the announcement or pendency of the Merger on NewLink's, Lumos' or the combined company's business relationships, operating results and business generally;
- risks that the Merger disrupts current plans and operations of NewLink, Lumos or the combined company;
- risks related to diverting management's attention from NewLink's ongoing business operations;

- other business effects, including the effects of industry, market, economic, political or regulatory conditions, future exchange and interest rates, and changes in tax and other laws, regulations, rates and policies;
- the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data;
- the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities;
- risks that NewLink or the combined company will fail to satisfy Nasdaq listing requirements;
- risks related to cost reduction efforts;
- NewLink's workforce reduction costs may be greater than anticipated and the workforce reduction may have an adverse impact on NewLink's development activities; and
- the outcome of any legal proceedings that may be instituted against NewLink, Lumos or the combined company related to the Merger Agreement or the Merger.

For further discussion of these and other risks, contingencies and uncertainties applicable to us, see "Risk Factors" beginning on page 17 and in our other filings with the SEC incorporated by reference into this proxy statement. See also "Where You Can Find More Information" beginning on page 166 for more information about the SEC filings incorporated by reference into this proxy statement.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We are not under any obligation, and we expressly disclaim any obligation, to update, alter, or otherwise revise any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future events or otherwise, except as may be required by law.

THE SPECIAL MEETING

Date, Time, Place

The Special Meeting will be held on March 17, 2020 at 9:00 a.m. local time at ISU Economic Development Core Facility, 1805 Collaboration Place, Ames, IA 50010.

Purposes of the NewLink Special Meeting

At our Special Meeting, stockholders will act upon the matters outlined in the accompanying notice, including the following:

- the Merger Proposal;
- the Reverse Stock Split Proposal;
- the Compensation Proposal; and
- the Adjournment Proposal.

Other than the proposals noted above, we do not expect a vote to be taken on any other matters at the Special Meeting or any adjournment or postponement thereof. However, if any other matters are properly presented at the Special Meeting or any adjournment or postponement thereof for consideration, the holders of the proxies solicited by this proxy statement will have discretion to vote on such matters in accordance with applicable law and their judgment.

Recommendation of the NewLink Board

The NewLink Board unanimously recommends that stockholders vote "FOR" the Merger Proposal, "FOR" the Reverse Stock Split Proposal, "FOR" the Compensation Proposal and "FOR" the Adjournment Proposal. In reaching its decision to approve the Merger, the Merger Agreement, the issuance of NewLink's common stock pursuant to the Merger Agreement and the resulting "change of control" of NewLink under Nasdaq rules and the transactions contemplated by the Merger and to recommend that you vote in the manner noted above, the NewLink Board considered a wide range of material factors relating to the Merger and consulted with management and outside financial and legal advisors. For more information on these factors see "The Merger — NewLink's Reasons for the Merger" and "— Recommendations of the NewLink Board" beginning on pages 66 and 68, respectively.

Record Date and Voting Power

Holders of our common stock as of the close of business on the record date, February 7, 2020, are entitled to notice of, and to vote at, the Special Meeting and any postponements or adjournments of the Special Meeting. At the close of business on the record date, there were 37,328,425 shares of our common stock outstanding and entitled to vote at the Special Meeting. No other shares of capital stock were outstanding on the record date.

Each share of our common stock issued and outstanding as of the close of business on the record date is entitled to one vote.

Quorum

The presence, in person or by proxy, of the holders of a majority of the shares of the stock entitled to vote at the Special Meeting is necessary to constitute a quorum to transact business. There must be a quorum for business to be conducted at the Special Meeting. However, even if a quorum does not exist, the chair of the Special Meeting may adjourn the Special Meeting to another place, date and time.

Once a share is represented in person or by proxy at the Special Meeting, it will be counted for purposes of determining whether a quorum exists at the Special Meeting and any adjournment or postponement of the Special Meeting. However, if a new record date is set for the adjourned or postponed Special Meeting, a new quorum will have to be established. For purposes of determining the presence of a quorum, abstentions will be counted as present at the Special Meeting.

Required Vote

Proposal 1: Merger Proposal

The approval of the Merger Proposal requires the affirmative vote of the majority of the votes cast affirmatively or negatively on the Merger Proposal.

Holders of our common stock may vote "FOR," "AGAINST" or "ABSTAIN" with respect to the Merger Proposal.

Proposal 2: Reverse Stock Split Proposal

The approval of the Reverse Stock Split Proposal requires the affirmative vote of the majority of the outstanding shares of NewLink's common stock entitled to vote at the Special Meeting.

Holders of our common stock may vote "FOR," "AGAINST" or "ABSTAIN" with respect to the Reverse Stock Split Proposal.

Proposal 3: Compensation Proposal

The approval of the Compensation Proposal requires the affirmative vote of the majority of the votes cast affirmatively or negatively on the Compensation Proposal.

Holders of our common stock may vote "FOR," "AGAINST" or "ABSTAIN" with respect to the Compensation Proposal.

Proposal 4: Adjournment Proposal

The approval of the Adjournment Proposal requires the affirmative vote of a majority of the votes cast affirmatively or negatively on the Adjournment Proposal.

Holders of our common stock may vote "FOR," "AGAINST" or "ABSTAIN" with respect to the Adjournment Proposal.

Voting and Revocation of Proxies

Voting by Stockholders

Your vote is very important to us and we hope that you will attend the Special Meeting. However, whether or not you plan to attend the Special Meeting, please vote by proxy in accordance with the instructions on your proxy card or voting instruction card (from your broker, bank or other agent). There are three convenient ways of submitting your vote:

- *By Telephone or Internet* — All record holders can vote by touchtone telephone from the United States using the toll free telephone number on the proxy card, or over the internet, using the procedures and instructions described on the proxy card. "Street name" holders may vote by telephone or internet if their bank, broker or other agent makes those methods available, in which case the bank, broker or other agent will enclose the instructions with the proxy materials. The telephone and internet voting procedures are designed to authenticate stockholders' identities, to allow stockholders to vote their shares, and to confirm that their instructions have been recorded properly.
- *In Person* — All record holders may vote in person at the Special Meeting. If you hold your shares in "street name" you will receive instructions from your broker, bank or other agent describing how to vote your shares. If you hold shares in "street name" and do not receive instructions on how to vote your shares, you should contact your broker, bank or other agent promptly and request this information. You will need to bring the broker, bank or other agent issued proxy with you to the Special Meeting and hand it in with a signed ballot that will be provided to you at the Special Meeting. You will not be able to vote your shares without an agent issued proxy. Note that a broker letter that identifies you as a stockholder is not the same as an agent issued proxy.
- *By Written Proxy* — All record holders can vote by written proxy card. If you are a "street name" holder, you will receive a voting instruction form from your bank, broker or other agent.

The NewLink Board has appointed Carl W. Langren, Bradley J. Powers and Ryan D. Trytten, or any of them, to serve as the proxies for the Special Meeting.

Even if you currently plan to attend the Special Meeting, we recommend that you vote by telephone or internet or return your proxy card or voting instruction form as described above so that your votes will be counted if you later decide not to attend the Special Meeting or are unable to attend.

Abstentions

Assuming a quorum is present, abstentions will have no effect on the outcome of the Merger Proposal (Proposal 1), the Compensation Proposal (Proposal 3) or the Adjournment Proposal (Proposal 4).

Abstentions will have the same effect as a vote "AGAINST" the Reverse Stock Split Proposal (Proposal 2).

For purposes of determining the presence of a quorum, abstentions will be counted as present at the Special Meeting.

Broker Non-Votes

Brokers, banks or other agents who hold shares in "street name" for their customers have authority to vote those shares on "routine" proposals when they have not received instructions from the beneficial owners of such shares. However, brokers, banks or other agents do not have the authority to vote shares they hold for their customers on "non-routine" proposals when they have not received instructions from the beneficial owners of such shares.

Broker non-votes occur when shares are held in "street name" through a broker, bank or other agent on behalf of a beneficial owner, and the broker submits a proxy but does not vote for a matter because the broker has not received voting instructions from the beneficial owner and the broker does not have discretionary voting authority on the matter. Under applicable stock exchange rules, brokers are permitted to exercise discretionary voting authority only on "routine" matters when voting instructions have not been timely received from a beneficial owner. The Reverse Stock Split Proposal and the Adjournment Proposal are considered "routine" matters. Therefore, if you do not provide voting instructions to your broker regarding any of these proposals, your broker will be permitted to exercise discretionary voting authority to vote your shares on such proposals. The Merger Proposal and the Compensation Proposal are considered "non-routine" matters. Therefore, if you do not provide voting instructions to your broker regarding any of these proposals, your broker will not be permitted to exercise voting authority to vote your shares on such proposals and will result in a broker non-vote. Broker non-votes will have no effect on the outcome of the Merger Proposal or the Compensation Proposal.

Failure to Vote

If you are a stockholder of record and you do not vote at the Special Meeting in person or properly return your proxy card or vote over the internet or by phone, your shares will not be voted at the Special Meeting, will not be counted as present in person or by proxy at the Special Meeting and will not be counted for purposes of determining whether a quorum exists.

As discussed above, brokers, banks and other agents do not have discretionary voting authority with respect to the Merger Proposal or the Compensation Proposal. Accordingly, if you are the beneficial owner of shares held in "street name" and you do not issue voting instructions to your broker, bank or other agent with respect to any such proposals, your shares will not be voted with respect to such proposals. If you are the beneficial owner of shares held in "street name" and you do not issue voting instructions to your broker, bank or other agent with respect to the Reverse Stock Split Proposal or the Adjournment Proposal, your broker will have discretionary authority to vote your shares with respect to such proposals.

A failure to vote, either by you, or with respect to "routine" matters for which no broker instruction is given, your broker, will have the same effect as a vote "AGAINST" the approval of the Reverse Stock Split Proposal but, assuming a quorum is present, will have no effect on the outcome of the Merger Proposal, the Compensation Proposal or the Adjournment Proposal.

Proxies; Revocation of Proxies

Proxies that are signed and returned by a stockholder of record without voting instructions will be voted "FOR" the Merger Proposal, the Reverse Stock Split Proposal, the Compensation Proposal and the Adjournment Proposal in accordance with the recommendation of the NewLink Board.

If you are a record holder, you may revoke your proxy at any time by any of the following means:

- You may send a timely written notice that you are revoking your proxy to our Secretary at 2503 South Loop Drive, Suite 5100, Ames, IA 50010;
- You may submit another properly completed proxy card with a later date;
- You may grant a subsequent proxy by telephone or via the internet; or
- You may attend the Special Meeting and vote in person (simply attending the meeting will not, by itself, revoke your proxy).

Your most current proxy card or telephone or internet proxy is the one that is counted.

If your shares are held by your broker or bank as a nominee or agent, you should follow the instructions provided by your broker or bank.

Adjournments

The Special Meeting may be adjourned for any purpose, including for the purpose of obtaining a quorum or soliciting additional votes if there are insufficient votes to authorize the Merger Proposal, the Reverse Stock Split Proposal or the Compensation Proposal. Any adjournment may be made without notice (if the adjournment is not for more than 30 days and a new record date is not fixed for the adjourned meeting), by an announcement made at the Special Meeting of the time, date and place of the adjourned meeting. Any adjournment will allow stockholders of record who have already sent in proxies to revoke them at any time prior to their use at the Special Meeting, as adjourned. See “Proposal 4: Approval of the Adjournment Proposal” on page 106 for more information concerning the adjournment of the Special Meeting.

Solicitation of Proxies

This proxy solicitation is being made by us on behalf of the NewLink Board. We will bear the costs of soliciting proxies. We have engaged The Proxy Advisory Group, LLC to assist in the solicitation of proxies and provide related advice and informational support for a services fee and customary disbursements, which are not expected to exceed $50,000 in total.

The solicitation of proxies will initially be made by mail. Forms of proxies and proxy materials may also be distributed through brokers, banks and other agents to the beneficial owners of our common stock, in which case such parties will be reimbursed for their reasonable out-of-pocket expenses. Proxies may also be solicited in person or by telephone, facsimile, electronic mail or by certain of our directors, officers or employees. Any of our directors, officers or employees participating in the solicitation will not receive additional compensation for their efforts but will be reimbursed for out-of-pocket expenses.

Other Matters

At this time, we know of no other matters to be submitted at the Special Meeting.

Independent Auditor’s Attendance

Representatives of KPMG LLP are not expected to be present at the Special Meeting.

THE MERGER

This section and "The Merger Agreement" beginning on page 90 of this proxy statement describe the material aspects of the Merger, including the Merger Agreement. While NewLink believes that this description covers the material terms of the Merger and the Merger Agreement, it may not contain all of the information that is important to you. You should read carefully this entire proxy statement, including the Merger Agreement, which is attached as Annex A to this proxy statement, and the other documents to which NewLink has referred to or incorporated by reference herein. For a more detailed description of where you can find those other documents, see "Where You Can Find More Information" beginning on page 166 of this proxy statement.

Background of the Merger

The terms of the Merger Agreement are the result of extensive arm's-length negotiations among the management teams of NewLink and Lumos, and their representatives, under the guidance of each company's board of directors. The following chronology summarizes the key meetings and events that led to the signing of the Merger Agreement. This chronology does not purport to catalogue every conversation among the NewLink Board or the representatives of NewLink, Lumos, and other parties.

The NewLink Board and NewLink management regularly review and evaluate NewLink's business and operations, strategy and prospects with a view toward enhancing stockholder value. As part of this evaluation, the NewLink Board has, from time to time, considered a variety of strategic alternatives to NewLink's business strategies, including consideration of potential changes to NewLink's strategy and direction, potential partnerships and other strategic transactions and potential acquisitions.

During the course of these regular reviews, NewLink management and Lumos management held an informal meeting in January 2018.

In April 2018, a NewLink competitor announced negative results of a pivotal trial that evaluated its enzymatic IDO1 inhibitor in combination with a PD-1 therapy for metastatic melanoma patients. In cancer, the indoleamine-2, 3-dioxygenase ("IDO") pathway regulates immune response by suppressing T-cell activation, which enables cancer to avoid immune response. IDO pathway inhibitors function to reverse the immunosuppressive effects of low tryptophan and high kynurenine that result from IDO activity. While indoximod, NewLink's IDO1 pathway inhibitor, works differently than the competitor's enzymatic inhibitor, the investor sentiment toward IDO inhibitors as a class was negatively affected by news of the competitor's negative trial results, resulting in downward pressure on the NewLink stock price following the announcement of the competitor's IDO1 enzymatic inhibitor failure.

On April 10, 2018, the NewLink Board met with NewLink management and representatives of Cooley LLP ("Cooley"), outside counsel to NewLink, and discussed the competitor's clinical trial failure and its implications for NewLink's clinical development programs. Thereafter, NewLink initiated an internal review of all clinical trials and programs and reduced its ongoing clinical development activities.

Also, in April 2018, a financial advisor to Party A introduced Party A to NewLink as a potential strategic partner. No formal discussions between NewLink and Party A regarding a potential business combination occurred until September 2018.

On May 22 and May 23, 2018, the NewLink Board met with NewLink management and representatives of Cooley and discussed potential strategic changes to the NewLink business in light of the competitor's clinical trial failure.

Thereafter, NewLink's business development team began evaluating strategic opportunities perceived to have the potential to be transformative to NewLink. Beginning in June 2018, NewLink initiated a weekly "External Opportunity Review" where a variety of strategic alternatives were reviewed by NewLink's executive management team. Opportunities were evaluated on the basis of strategic flexibility, diversification of risk and the potential to increase stockholder value, as well as additional criteria, including the strength of the respective company's underlying science, strength of available data, length of timeline to data that could serve as a catalyst for financing transactions, and the amount of capital required to achieve such financial catalyst. NewLink management focused its evaluation on other oncology and pharmaceutical companies because of NewLink's expertise in evaluating opportunities within those industries and the significant additional time and expense that would have been required to assess opportunities in other industries. During this process, NewLink management reviewed 30 companies that management believed could be attractive strategic partners for NewLink and NewLink entered into nondisclosure agreements with seven of those companies. The depth of evaluation undertaken by NewLink management with

respect to the potential strategic partners varied based on the perceived value of the respective opportunities, and included conducting diligence and contracting with external experts to assist in evaluating the opportunities. Following this process, NewLink's management team identified three companies (Lumos, Party B and Party C) that they believed warranted further assessment as potential strategic partners. Between August and September, 2019, NewLink received several other inquiries or proposals that NewLink's management analyzed using the same criteria noted above. Based on that review, NewLink's management reported to the NewLink Board of management's analysis and did not recommend that the NewLink Board consider any of the additional inquiries or proposals. In light of the recommendations of NewLink's management, the NewLink Board took no further action on these inquiries and proposals.

On June 27, 2018, former NewLink CEO, Charles Link, Jr. met with Lumos management for a preliminary discussion regarding a potential strategic transaction involving the two companies.

On July 25 and July 26, 2018, the NewLink Board met with NewLink management and representatives of Cooley and discussed potential strategic changes to the NewLink business and potential strategic opportunities.

In August 2018, NewLink management held several meetings with representatives of Lumos. During these meetings, senior leadership of both NewLink and Lumos explored a potential business combination.

Between August 2018 and November 2018, NewLink and Lumos continued negotiations with respect to a potential business combination between the parties. On October 20, 2018, Lumos sent NewLink a draft non-binding letter of intent contemplating that Lumos equityholders would exchange their Lumos equity for shares of the combined company at an exchange ratio that would result in Lumos equityholders owning 56% of the combined company post-Merger, with such exchange ratio subject to adjustment if NewLink's cash position at closing was greater than $122 million or less than $112 million. The letter also contemplated that if NewLink or Lumos breached the exclusivity provisions of the definitive merger agreement or provided notice of termination to the other party for any reason that the breaching or terminating party would be required to pay the other party $4 million, and such termination fee would not be an exclusive remedy to the parties. On November 7, 2018, NewLink responded to Lumos' draft by proposing that Lumos equityholders would be issued shares of the combined company at an exchange ratio that would result in Lumos equityholders holding 50% of the combined company post-Merger, without an adjustment for NewLink's cash position at closing, and a termination fee limited to the anticipated transaction costs of the parties payable under limited circumstances, with such termination fee serving as the exclusive remedy to the parties.

On November 15, 2018, Lumos responded to NewLink's draft by proposing that Lumos equityholders will hold a percentage that will be later determined of the combined company as opposed to 50% in NewLink's proposal, and a termination fee of $4 million payable under broader circumstances than NewLink's proposal in the November 7, 2018 letter of intent. The parties were unable to reach consensus on a business strategy for the combined entities at that time and no further drafts of the letter of intent were exchanged in 2018.

On September 19, 2018, representatives from NewLink and Party A met for an introductory teleconference and discussed their respective businesses, strategic plans for clinical trials and a potential business combination. Following the meeting, the parties continued to exchange information relating to their respective businesses and began discussions of a potential business combination.

On October 29 and October 30, 2018, the NewLink Board met with NewLink management and representatives of Cooley and discussed the process undertaken by management to date to evaluate potential strategic opportunities and the criteria for evaluating potential strategic partners. At the meeting, the NewLink Board also discussed and assessed a number of potential strategic opportunities, which included Party A, Lumos, Party B, Party C and a fifth party.

During the second half of 2018, NewLink management conducted teleconferences and meetings with representatives of Party B to discuss a potential business combination. The parties did not reach an agreement on a preliminary set of terms and conditions and NewLink determined not to pursue further discussions.

During the second half of 2018, NewLink management also conducted teleconferences with representatives of Party C to discuss a potential business combination. Following initial discussions, Party C and NewLink determined not to pursue further discussions.

Throughout the fourth quarter of 2018, executive management and senior leadership from Party A and NewLink met face-to-face and via teleconferences to discuss clinical priorities of the respective companies, analyze one

another's research and development pipelines, and begin due diligence efforts. Also, during November and December 2018, the NewLink Board held multiple meetings with management and representatives of Cooley to discuss a potential business combination with Party A. These meetings and teleconferences culminated in a non-binding letter of interest executed by Party A and NewLink on December 20, 2018 that included a mutual exclusivity provision expiring on the earliest of February 28, 2019, written notification by one party to the other party that there was no longer an interest in a transaction between the parties and such later date as the parties would agree in writing.

In January 2019, a team of NewLink executives and senior managers traveled to Party A's principal place of business, where the parties discussed corporate strategy and clinical development plans for a potential combined entity as well as due diligence items.

On January 28, 2019, NewLink sent Party A an initial draft of a share purchase agreement, which proposed the purchase by NewLink of the outstanding capital stock of Party A from Party A's stockholders in exchange for issuance by NewLink of shares of its common stock to those stockholders.

From mid-January 2019 through the end of May 2019, Cooley and NewLink continued their due diligence review of Party A. From late-February through May 2019, the NewLink Board met regularly with management and representatives of Cooley to discuss the status of negotiations with, and due diligence matters regarding, Party A.

On March 6, 2019, a team of NewLink executives and senior managers traveled to Party A's principal place of business and engaged in further discussions about due diligence matters. Following this visit and throughout March 2019, additional teleconferences took place between executive officers of NewLink and Party A regarding due diligence matters and proposed transaction terms.

On March 29, 2019, Party A responded to the initial draft of the share purchase agreement. Given the significant differences between Party A's revision to the draft share purchase agreement and the terms set forth in the initial letter of intent, the parties negotiated and entered into a new, non-binding letter of interest dated April 9, 2019 that included a mutual exclusivity provision expiring on the earliest of May 10, 2019, written notification by one party to the other party that there was no longer an interest in a transaction between the parties and such later date as the parties would agree in writing.

Throughout April 2019, the two parties continued negotiating terms of the draft share purchase agreement as well as expanding supplemental due diligence reviews.

In May 2019, following release of data related to a clinical trial involving one of Party A's investigational product candidates, NewLink discussed with Party A alternative structures for a transaction. Ultimately, NewLink and Party A were unable to reach agreement on the terms of a proposed business combination and the parties ended their discussions in June 2019.

On June 25, 2019, Dr. Link met with Lumos CEO, Rick Hawkins, to discuss a potential business combination between NewLink and Lumos.

On July 9, 2019, Lumos provided NewLink with an updated draft of the letter of intent. The letter proposed a 50/50 equity split of the combined company between pre-Merger NewLink and Lumos equityholders and a termination fee payable under specified circumstances of $4 million.

On July 11, 2019, Lumos management hosted a teleconference with NewLink management to introduce key members of the Lumos organization, share business information, and to provide an overview of their therapeutic development programs and strategy. Over the next several days, representatives from NewLink and Lumos continued to meet and discuss a potential business combination.

On July 16, 2019, NewLink executives and senior managers traveled to Lumos' principal place of business to discuss matters relating to their respective businesses and strategies and to determine whether they believed a potential business combination was feasible from a strategic perspective.

On July 19, 2019, NewLink responded to Lumos' draft letter of intent, which response provided that Lumos stockholders (rather than all of its equityholders) would be issued 50% of the equity of the combined company and the termination fee would be limited to the non-terminating party's reasonable costs and expenses actually incurred as of the date of the event.

Also on July 19, 2019, NewLink and Lumos entered into a mutual confidential disclosure agreement and throughout the remainder of July 2019, each of NewLink and Lumos conducted a due diligence review of the other party.

On July 22, 2019, Lumos responded to NewLink's revisions to the draft letter of intent, which included revising the proposed termination fee to $2 million.

On July 25, 2019, NewLink responded to Lumos' draft letter of intent. Such response limited the termination fee to the non-terminating party's reasonable costs and expenses actually incurred as of the date of the event, up to a cap of $2 million. On the same day, Mr. Hawkins and John McKew, Ph.D., CSO of Lumos, presented the potential combined business strategy to the NewLink Board, and the NewLink Board approved the letter of intent. In considering the relative values of NewLink and Lumos, neither NewLink management nor the NewLink Board attributed any value to future royalty payments that NewLink might be eligible to receive under NewLink's Merck Agreement because NewLink management and the NewLink Board did not believe any such royalties would be payable to NewLink in the foreseeable future, if ever, as a result of the royalty terms of the Merck Agreement and, other than with respect to the Ebola vaccine V920 product candidate, the status of the development of the compounds and product candidates subject to the agreement.

On July 26, 2019, the two parties executed the letter of intent for the Merger that was presented to the NewLink Board on July 25, 2019, which also included a mutual exclusivity provision providing for an exclusivity period of 45 days.

On July 30, 2019, NewLink announced financial results for the second quarter ended June 30, 2019 and announced that Dr. Link, was retiring from his posts as Chairman, Chief Executive Officer and Chief Science Officer of NewLink and resigning from the NewLink Board, effective August 3, 2019. NewLink also announced that the NewLink Board had established the Office of the CEO, comprised of Carl W. Langren, Chief Financial Officer; Eugene P. Kennedy, M.D., Chief Medical Officer; Bradley J. Powers, General Counsel; and Lori D. Lawley, Vice President, Finance and Controller, to lead NewLink, effective August 3, 2019.

On August 6, 2019, Cooley emailed a draft Merger Agreement to DLA Piper, outside legal counsel to Lumos. On August 13, 2019, Lumos responded with its comments to the draft of the Merger Agreement. Throughout the remainder of August and September 2019, representatives of NewLink, Lumos, Cooley and DLA Piper continued to negotiate and exchange revised drafts of the Merger Agreement and the other transaction documents, including the forms of Support Agreement and Lock-Up Agreement.

During the course of the negotiations in August and September 2019, the parties exchanged drafts of the Merger Agreement and such drafts included negotiation on termination fee amounts payable under specified circumstances as follows:

- The August 6, 2019 draft of the Merger Agreement delivered by NewLink, consistent with the executed letter of intent, contemplated a termination fee payable by NewLink or Lumos under specified circumstances relating to a failure to obtain the required stockholder vote of NewLink's or Lumos' stockholders, respectively, in an amount to cover a reasonable costs and expenses actually incurred as of the date of the event, up to a cap of $2 million;
- On August 13, 2019, Lumos' draft Merger Agreement increased the termination fee from the terms agreed to in the executed letter of intent to require that NewLink pay an additional $5 million in addition to Lumos' transaction expenses where NewLink stockholders failed to approve the NewLink stockholder matters by the required NewLink stockholder vote;
- On August 29, 2019, NewLink rejected Lumos' August 13 proposal for NewLink to pay an additional $5 million where NewLink stockholders failed to approve the NewLink stockholder matters by the required NewLink stockholder vote and limited the termination fee to Lumos' transaction expenses;
- On September 1, 2019, Lumos revised the Merger Agreement to provide that, where Lumos terminates the Merger Agreement because the NewLink Board effects a NewLink Board Adverse Recommendation Change or if NewLink fails to comply in all material respects with its obligations to hold its stockholder meeting, that NewLink will pay Lumos' transaction expenses and an additional $2.5 million; and
- On September 5, 2019, NewLink revised the termination fee payable under all specified circumstances to $2 million, regardless of transaction expenses.

The draft Merger Agreement was periodically revised with respect to the provisions governing the issuance of consideration, including establishing different allocation ratios for Lumos common stock, Series A Preferred Stock and Series B Preferred Stock with respect to NewLink's common stock, but remained consistent with the executed letter of intent with respect to issuing approximately 50% of the post-closing combined company's common stock to pre-closing Lumos stockholders following the Merger.

While Stifel did not make any recommendations as to the form and amount of consideration in the Merger Agreement, Stifel did provide views on the structure and magnitude of the termination fee during the course of the negotiations.

Throughout August 2019, representatives from NewLink and Lumos continued to meet telephonically to discuss the combined company's potential corporate strategy and clinical development plans and to work through due diligence items. During these meetings, the representatives discussed a combined company development plan primarily focused on development of Lumos' sole product candidate, LUM-201.

On August 14, 2019, NewLink executives and senior management traveled to Lumos' principal place of business to meet with executives and senior management of Lumos to further discuss the combined company's potential corporate strategy and operational plans, and to develop draft pro forma financial forecasts.

On August 16, 2019, NewLink engaged Stifel as NewLink's exclusive financial advisor for the potential Merger.

On August 28, 2019, executives from Lumos and NewLink held a meeting with representatives from Stifel present. Attendees discussed the draft pro forma financial forecasts of the combined company.

During August and September 2019, the outside directors of NewLink held weekly teleconferences at which management and representatives of Cooley provided updates on the due diligence review of Lumos and progress in negotiating the terms of the proposed business combination.

On September 9, 2019, the NewLink Board met with NewLink management and representatives of Stifel and Cooley. Representatives of Stifel presented their preliminary draft valuation analysis of Lumos and NewLink. NewLink management presented the proposed combined company clinical development plan focused on development of LUM-201 and a preliminary, three-year pro forma financial expense forecast for the combined company. NewLink management also reviewed its preliminary plans for a restructuring plan and reduction in workforce in the context of the potential Merger, and presented recommendations for the treatment of stock options for employees who would be terminated and those who would be continuing and for members of the NewLink Board. The NewLink Board discussed the status of NewLink's executive employment agreements and determined that the Merger should be considered a "change of control" under such employment agreements. The NewLink Board also discussed the proposed pro forma capitalization of the combined company. The NewLink Board also reviewed NewLink's 2019 corporate goals and discussed potential revision of such goals.

On September 10, 2019, the NewLink Board, with representatives of management and Cooley present, continued its discussion of the Merger terms, the proposed restructuring plan and reduction in workforce, 2019 corporate goals and the proposed pro forma capitalization of the combined company. The NewLink Board provided guidance to management and Cooley regarding the negotiation of matters affecting the pro forma capitalization table of the combined company. The NewLink Board also discussed appropriate changes to NewLink's strategic goals and development plans in light of the current business circumstances.

On September 12, 2019, the NewLink Board met with NewLink management and representatives of Cooley and received an update on the status of negotiations with Lumos. The NewLink Board approved, subject to the signing of the Merger Agreement, (i) the acceleration of vesting of equity awards granted under the 2009 Equity Plan by, with respect to continuing employees, 12 months upon closing of the Merger, with respect to terminating employees, 12 months upon their respective termination dates, and with respect to resigning NewLink Board members, 100% upon closing of the Merger, and (ii) the extension of the exercise period for terminating employees and resigning NewLink Board members to allow each to exercise his or her respective options to purchase any vested shares on or before the one-year anniversary of their termination or resignation dates, respectively.

On September 30, 2019, the NewLink Board met with NewLink management and with representatives of Stifel and Cooley. Representatives of Stifel delivered to the NewLink Board Stifel's oral opinion, subsequently confirmed in writing by delivery of a written opinion dated September 30, 2019, which is referred to herein as the Opinion, that, as of that date, and based upon and subject to the assumptions made, procedures followed, matters considered and

qualifications and limitations of review set forth therein, the Merger Consideration in the Merger pursuant to the Merger Agreement was fair to NewLink from a financial point of view. Representatives of Cooley reviewed the terms of the Merger Agreement. Following extensive discussion of the foregoing by the NewLink Board, the NewLink Board unanimously (i) approved the Merger Agreement and consummation of the Merger upon the terms and subject to the conditions set forth in the Merger Agreement, (ii) determined that the terms of the Merger Agreement and the transactions contemplated by the Merger Agreement, including the Merger, are fair to, advisable and in the best interests of NewLink and its stockholders, (iii) directed that (1) the amendment of the Company's Charter to effect a reverse stock split, (2) the issuance of the shares of the Company's common stock to Lumos stockholders in connection with the Merger and (3) change of control of the Company resulting from the Merger pursuant to the Nasdaq rules be submitted to NewLink's stockholders for approval at the Special Meeting, and (iv) recommended that NewLink stockholders approve the foregoing matters. The NewLink Board also approved (x) amended and restated bylaws for NewLink to, among other changes, add an exclusive forum provision, (y) restatements of the form of NewLink's employment agreements for executives and senior management to, among other things, provide that the Merger would be a "change of control" for purposes of the agreements, and (z) severance arrangements for employees to be terminated in the reorganization. The NewLink Board also ratified the separation agreement between NewLink and Dr. Nicholas Vahanian, NewLink's former President and a former member of the NewLink Board who retired on September 27, 2019.

On September 30, 2019, each of Lumos, NewLink, and Merger Sub executed and delivered the Merger Agreement, effective as of September 30, 2019, each of the officers and directors of NewLink and Stine Seed Farm, Inc. ("Stine"), a significant stockholder of NewLink, entered into a support agreement with NewLink and Lumos (as more fully described in "Ancillary Agreements Related to the Merger — Support Agreements"), and each of the officers and directors of NewLink, Stine, and each of the officers, directors and certain stockholders of Lumos entered into a lock-up agreement with NewLink (as more fully described in "Ancillary Agreements Related to the Merger — Lock-Up Agreements"). On September 30, 2019, Lumos stockholders also approved the Merger and the Merger Agreement.

On October 1, 2019, NewLink and Lumos issued a joint press release announcing the execution of the Merger Agreement and the proposed Merger.

Evercel Proposals

On October 25, 2019, several members of the NewLink Board received a letter dated October 24, 2019 from Daniel Allen, CEO of Evercel, Inc. ("Evercel"), setting forth a number of objections to the proposed Merger and proposing that NewLink instead merge with Evercel in a transaction in which the stockholders of NewLink and Evercel would each own approximately 50% of the combined entity and with the combined entity being run by the Evercel management team ("Evercel Proposal #1"). The letter proposed that Evercel enter into a nondisclosure agreement, raised the possibility that a one-time dividend of unspecified magnitude might be paid to NewLink stockholders at the closing of such transaction and offered that Evercel would cover the $2 million break-up fee payable under the terms of the Merger Agreement should NewLink accept such proposal.

At a regularly scheduled meeting of the NewLink Board held on November 5, 2019, the NewLink Board met with representatives of Stifel and Cooley to discuss Evercel Proposal #1. After consulting with Stifel and Cooley, the NewLink Board unanimously concluded that Evercel Proposal #1 did not constitute, and was not reasonably likely to result in, a Superior Offer (as defined in the Merger Agreement). On November 6, 2019, Mr. Langren sent an email to Mr. Allen acknowledging receipt of the October 24, 2019 letter and noting the provisions of the Merger Agreement governing the consideration of alternative proposals.

On November 25, 2019, several members of the NewLink Board received a letter dated November 25, 2019 from Mr. Allen setting forth additional objections to the proposed Merger and proposing two alternative transactions: (1) an offer by Evercel to acquire 100% of the outstanding shares of NewLink common stock for $1.00 per share and 0.3 shares of common stock of Evercel per share of NewLink common stock ("Evercel Proposal #2") and (2) an offer by Evercel to acquire 100% of NewLink's outstanding shares of common stock for $1.75 per share in cash ("Evercel Proposal #3"). Under both proposals, the combined entity would be run by the Evercel management team. The letter proposed that Evercel enter into a nondisclosure agreement.

At a telephonic meeting of the NewLink Board held on December 3, 2019, the NewLink Board met with representatives of Stifel and Cooley to discuss Evercel Proposals #2 and #3. After reviewing an analysis of both proposals by Stifel, and consulting with Stifel and Cooley, the NewLink Board unanimously concluded that neither Evercel Proposal

#2 nor Evercel Proposal #3 constituted, and neither was reasonably likely to result in, a Superior Offer (as defined in the Merger Agreement). On December 4, 2019, Mr. Powers sent an email to Mr. Allen reporting that determination and again noting the provisions of the Merger Agreement governing consideration of alternative proposals.

On December 12, 2019, Evercel issued a press release to announce the rejected offer to acquire NewLink.

On December 16, 2019, NewLink issued a press release in response, announcing that the NewLink Board continued to believe that the planned Merger is in the best interest of the NewLink stockholders, and noted that the Evercel proposal did not satisfy the requirements in the Merger Agreement for granting due diligence access or commencing negotiations with respect to a competing proposal.

On January 30, 2020, Dr. Raffin and NewLink management received a letter dated January 29, 2020 from Mr. Allen in which Evercel offered to acquire 100% of NewLink's outstanding shares of common stock for $2.00 per share in cash ("Evercel Proposal #4"). The letter also indicated that Evercel would be willing to discuss other transaction structures.

At a telephonic meeting of the NewLink Board held on February 3, 2019, at which all directors except Mr. Talarico were present, the NewLink Board discussed Evercel Proposal #4 with representatives of Stifel and Cooley. After reviewing an analysis of such proposals prepared by Stifel, and consulting with Stifel and Cooley, the NewLink Board unanimously concluded that Evercel Proposal #4 did not constitute, and was not reasonably likely to result in, a Superior Offer (as defined in the Merger Agreement).

NewLink's Reasons for the Merger

The following discussion sets forth material factors considered by the NewLink Board in reaching its determination to approve the terms and authorize the execution of the Merger Agreement for the purpose of effecting the Merger; however, it does not include all of the factors considered by the NewLink Board. In view of the wide variety of factors considered in connection with its evaluation of the Merger and the complexity of these matters, the NewLink Board did not find it useful to attempt, and did not attempt, to quantify, rank or otherwise assign relative weights to these factors. In considering the factors described above, individual members of the NewLink Board may have given different weight to different factors. The NewLink Board conducted an overall analysis of the factors described above, including thorough discussions with, and questioning of, NewLink's management team and the legal and financial advisors of NewLink, and considered the factors overall to be favorable to, and to support, its determination.

- The NewLink Board believes, based in part on the judgment, advice and analysis of NewLink management with respect to the potential strategic, financial and operational benefits of the Merger (which judgment, advice and analysis was informed in part on the business, technical, financial, accounting and legal due diligence investigation performed with respect to Lumos), that:
  - Lumos' sole product candidate, LUM-201, is potentially the first oral GH stimulating therapy for PGHD and other rare endocrine disorders;
  - the current standard of care for PGHD is a daily injection of rhGH and therefore an oral alternative could be received well by the market;
  - the combined company may be able to achieve cost savings and synergies from, among other things, reductions in corporate overhead and administrative costs in comparison to both companies on a stand-alone basis; and
  - the combined company will be led by experienced senior management from both NewLink and Lumos and a board of directors of seven members with three designated by NewLink, three designated by Lumos, and one to be designated following the Merger by the board of directors of the combined company.
- The NewLink Board also reviewed with the NewLink management Lumos' current plans for development of its sole product candidate to confirm the likelihood that the combined company would possess sufficient financial resources to enable it to implement its near-term business plans, including the Phase 2b clinical trial for LUM-201.

- The NewLink Board considered the opportunity as a result of the Merger for NewLink stockholders to participate in the potential increase in value that may result from the development of Lumos' sole product candidate and the potential increase in value of the combined company following the Merger.
- The NewLink Board considered Stifel's opinion to the NewLink Board that the Merger Consideration was fair, from a financial point of view, to NewLink, as more fully described below under the caption " — Opinion of NewLink's Financial Advisor."
- The NewLink Board also reviewed various factors impacting the financial condition, results of operations and prospects for NewLink, including:
  - the strategic alternatives of NewLink to the Merger, including potential transactions that could have resulted from discussions that NewLink management conducted with other potential strategic partners and the belief that the Merger with Lumos would provide NewLink stockholders with a greater potential opportunity to realize a return on their investment than any other alternative reasonably available to NewLink stockholders at that time;
  - the risks of continuing to operate NewLink on a stand-alone basis given concerns of investor sentiment toward IDO inhibitors as a class and the likelihood that market conditions for NewLink would not change for the benefit of NewLink stockholders in the foreseeable future on a stand-alone basis; and
  - the risks associated with NewLink's continued ability to maintain its Nasdaq listing as a stand-alone company.
- The NewLink Board also reviewed the terms and conditions of the proposed Merger Agreement, as well as the safeguards and protective provisions included therein intended to mitigate risks, including:
  - the fact that immediately following the Effective Time, Lumos stockholders will own approximately 50% of the outstanding common stock of the combined company, with NewLink stockholders holding approximately 50% of the outstanding common stock of the combined company;
  - the limited number and nature of the conditions to Lumos' obligation to consummate the Merger, including the absence of any financing contingency, and the limited risk of non-satisfaction of such conditions as well as the likelihood that the Merger will be consummated on a timely basis;
  - the respective rights of, and limitations on, NewLink and Lumos under the Merger Agreement to consider certain unsolicited acquisition proposals under certain circumstances should NewLink or Lumos receive a superior proposal;
  - the reasonableness of the potential termination fee payable by NewLink under certain circumstances of $2.0 million and the reasonableness of the potential termination fee payable by Lumos under certain circumstances of $2.0 million;
  - the support agreements, pursuant to which directors, officers and certain stockholders of NewLink agreed, solely in their capacity as stockholders, to vote their shares of NewLink's common stock in favor of the Merger Proposal, the Reverse Stock Split Proposal and the Compensation Proposal; and
  - the belief that the terms of the Merger Agreement, including the parties' representations, warranties and covenants, and the conditions to their respective obligations, are reasonable under the circumstances.

In the course of its deliberations, the NewLink Board also considered a variety of risks and other countervailing factors related to entering into the Merger, including:

- the substantial expenses to be incurred in connection with the Merger;
- the possible volatility, at least in the short term, of the trading price of NewLink's common stock resulting from the Merger announcement;
- the risk that the Merger might not be consummated in a timely manner or at all and the potential adverse effect of the public announcement of the Merger or any delay or failure to complete the Merger on the reputation of NewLink;
- the risk to NewLink's business, operations and financial results in the event that the Merger is not consummated;

- the strategic direction of the combined company following the completion of the Merger, which will be determined by the new board of directors of the combined company with substantial representation of Lumos' current directors;
- the fact that the Merger would give rise to substantial limitations on the utilization of NewLink's NOLs and various income tax credits; and
- various other risks associated with the combined company and the Merger, including those described in "Risk Factors" elsewhere in this proxy statement.

Recommendations of the NewLink Board

The NewLink Board has determined and believes that the Merger and the issuance of shares of NewLink's common stock pursuant to the Merger Agreement and the resulting "change of control" of NewLink under Nasdaq rules is in the best interests of NewLink and its stockholders and has approved such items. The NewLink Board recommends that NewLink stockholders vote "FOR" Proposal 1 to approve the issuance of shares of NewLink's common stock in the Merger and the resulting "change of control" of NewLink under Nasdaq rules.

The NewLink Board has determined and believes that it is advisable to, and in the best interests of, NewLink and its stockholders to approve the Charter Amendment to NewLink's Charter effecting the proposed reverse stock split, as described in this proxy statement. The NewLink Board recommends that NewLink stockholders vote "FOR" Proposal 2 to approve the Charter Amendment effecting the proposed reverse stock split, as described in this proxy statement.

The NewLink Board has determined and believes that it is advisable to, and in the best interests of, NewLink and its stockholders to approve, on an advisory basis, the executive compensation of Carl W. Langren, Eugene P. Kennedy, M.D. and Bradley J. Powers, as described in this proxy statement. The NewLink Board recommends that NewLink stockholders vote "FOR" Proposal 3 to approve the Compensation Proposal, as described in this proxy statement.

The NewLink Board has determined and believes that adjourning the Special Meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposals 1 (Merger Proposal) and 2 (Reverse Stock Split Proposal) is advisable to, and in the best interests of, NewLink and its stockholders and has approved and adopted the proposal. The NewLink Board recommends that NewLink stockholders vote "FOR" Proposal 4 to adjourn the Special Meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposals 1 or 2.

Interests of NewLink's Directors and Executive Officers in the Merger

In considering the recommendation of the NewLink Board that you vote to approve the Merger Proposal, you should be aware that NewLink's directors and executive officers have interests in the Merger that are different from, or in addition to, those of NewLink stockholders generally. The NewLink Board was aware of and considered these interests, among other matters, in evaluating and negotiating the Merger Agreement and the Merger, and in recommending that the Merger Proposal be approved by NewLink stockholders.

Assumptions

For purposes of this disclosure, "executive officers" refer to:

Name	Title
Eugene P. Kennedy, M.D.	Chief Medical Officer of NewLink
Carl W. Langren	Chief Financial Officer of NewLink
Bradley J. Powers	General Counsel of NewLink
Lori D. Lawley	Vice President, Finance and Controller of NewLink

The "named executive officers" refer to:

Name	Title
Charles J. Link, Jr., M.D.(1)	Former Chief Executive Officer and Chief Scientific Officer of NewLink
Carl W. Langren(2)	Chief Financial Officer of NewLink
Eugene P. Kennedy, M.D.	Chief Medical Officer of NewLink
Bradley J. Powers	General Counsel and current Principal Executive Officer of NewLink
Nicolas N. Vahanian, M.D.(1)	Former President of NewLink

(1) NewLink's former Chief Executive Officer and Chief Scientific Officer, Dr. Link, retired from his position as a NewLink executive and NewLink Board member on August 3, 2019, and its former President, Dr. Vahanian, retired from his position as President and as NewLink Board member on September 27, 2019.

(2) Mr. Langren was not a named executive officer for the year ended 2018. His information is included in this section to provide additional information to NewLink stockholders.

Severance and Change in Control Provisions of Employment Arrangements

On September 30, 2019, NewLink entered into amended and restated employment agreements (the "***Employment Agreements***") with its then-executive officers including Mr. Langren, Dr. Kennedy, Mr. Powers and Ms. Lawley. The Employment Agreements provide for severance payments and benefits in the event of a termination of employment by NewLink without "Cause" or resignation for "Good Reason" and enhanced severance benefits in the event of a termination of employment by NewLink without "Cause" or resignation for "Good Reason" within one month before or within 13 months following the occurrence of a "Change in Control" of NewLink. The Merger is deemed to be a "Change in Control" under the Employment Agreements.

The severance benefits of Dr. Kennedy, Mr. Powers and Ms. Lawley consist of:

(i) a lump sum payment equal to 12 months of the executive officer's then-current base salary,

(ii) a lump sum payment of the executive officer's target bonus for the year of termination,

(iii) 100% accelerated vesting and a 24-month extension of the exercise period of the executive officer's outstanding equity awards; and

(iv) reimbursement for COBRA coverage for up to 12 months after the separation date.

The severance benefits of Mr. Langren consist of:

(i) a lump sum severance payment equal to 18 months of Mr. Langren's then-current base salary;

(ii) a lump sum payment of an amount equal to the most recent bonus paid to Mr. Langren multiplied by 1.5;

(iii) 100% accelerated vesting and a 24-month extension of the exercise period of Mr. Langren's outstanding equity awards; and

(iv) reimbursement for COBRA coverage for up to 18 months after the separation date.

See "The Merger — Interests of NewLink's Directors and Executive Officers in the Merger — Golden Parachute Compensation" for more detail.

Board of Directors of the Combined Company

Pursuant to the Merger Agreement, NewLink and Lumos will use reasonable best efforts to take all necessary action so that immediately after the Effective Time, the board of directors of the combined company will consist of three members designated by NewLink, and three members designated by Lumos. One member is to be designated following the Merger by the board of directors of the combined company.

Executive Officers of the Combined Company

Pursuant to the Merger Agreement, NewLink and Lumos will use reasonable best efforts to take all necessary action so that immediately after the Effective Time, the following persons will be elected or appointed to the positions listed next to their names below to serve as executive officers of the combined company. Mr. Hawkins and Dr. McKew are currently executive officers of Lumos.

Name	Title
Richard J. Hawkins	Chief Executive Officer
Eugene P. Kennedy, M.D.	Chief Medical Officer
John McKew, Ph.D.	Chief Science Officer
Carl W. Langren	Chief Financial Officer
Bradley J. Powers	General Counsel
Lori D. Lawley	Vice President, Finance and Controller

Executive Officer Transitions

Dr. Link retired from his position as an executive of NewLink and a NewLink Board member on August 3, 2019. Pursuant to the terms of Dr. Link's separation agreement, Dr. Link is eligible to receive certain benefits, none of which is contingent upon or in connection with the Merger, including: (i) a pro-rated 2019 bonus payment based on actual 2018 bonus paid, (ii) a lump sum payment equal to 24 months of his current base salary, (iii) reimbursement for COBRA coverage for a period up to 18 months, and (iv) acceleration by 12 months of certain unvested stock options and restricted stock units. In addition, Dr. Link received an option grant for 331,258 shares of common stock which became exercisable beginning November 3, 2019, and extension of the post-termination exercise period by two years for certain vested options. Dr. Link is also eligible to receive up to 0.5% of the net amount realized by the Company from the monetization of the PRV. To be eligible for the separation benefits described above, Dr. Link must comply with his obligations under the separation agreement and provide a release of claims.

Dr. Vahanian retired from his position as President of NewLink and as a NewLink Board member on September 27, 2019, and remained an employee during the transition period through November 11, 2019, his separation date. Pursuant to the terms of Dr. Vahanian's transition agreement, Dr. Vahanian is eligible to receive certain benefits, none of which is contingent upon or in connection with the Merger, including: (i) a pro-rated 2019 bonus payment based on actual 2018 bonus paid, (ii) a lump sum payment equal to 18 months of his current base salary, (iii) COBRA coverage for a period up to 18 months, (iv) $400,000 as an allowance for future medical costs, healthcare insurance and rehabilitation expenses, and (v) acceleration by 12 months of certain unvested stock options and restricted stock units. In addition, Dr. Vahanian will receive an extension of the post-termination exercise period by two years for certain vested options. Dr. Vahanian is also eligible to receive up to 0.5% of the net amount realized by the Company from the monetization of the PRV. To be eligible for the separation benefits described above, Dr. Vahanian must comply with his obligations under the transition agreement and provide a release of claims.

The NewLink Board formed an Office of the CEO on July 28, 2019, and appointed Mr. Powers as our principal executive officer effective August 3, 2019.

Acceleration of Equity Awards

On September 12, 2019, the NewLink Board approved, subject to the signing of the Merger Agreement, a 12-month acceleration of vesting of equity awards granted under NewLink's 2009 Equity Incentive Plan (as amended, the "2009 Plan") held by all employees, including the executive officers of the Company, as well as 100% vesting of all outstanding equity awards granted under the 2009 Plan held by the resigning NewLink Board members who will resign effective as of the closing of the Merger. For continuing employees, which include NewLink's current executive officers, such acceleration will be effective as of the closing of the Merger. For terminating employees, such acceleration will be effective as of their respective termination dates. Terminating employees and resigning NewLink Board members will also receive an extension of their post-termination exercise periods such that they may exercise their respective awards to purchase any vested shares on or before the one-year anniversary of their respective termination date or resignation date, respectively.

The following table presents certain information concerning the outstanding NewLink options and RSUs held by NewLink's then-current directors and executive officers, as of December 31, 2019:

Name	Options/RSUs	Grant Date	Expiration Date	Exercise Price ($)	Numbers of Shares of NewLink Common Stock Underlying Options and RSUs as of December 31, 2019	Numbers of Shares of NewLink Common Stock Underlying Options and RSUs Vested as of December 31, 2019
Eugene P. Kennedy, M.D.	RSUs	1/4/2016	N/A	N/A	1,105	1,105
Eugene P. Kennedy, M.D.	Options	3/1/2019	2/28/2029	$ 1.80	185,000	40,468
Eugene P. Kennedy, M.D.	Options	7/31/2019	7/31/2026			

$
1.77

173,254

56,315

Lori D. Lawley
Options

8/1/2018

7/31/2028

$
3.17

25,000

14,583

Lori D. Lawley
Options

3/1/2019

2/28/2029

$
1.80

50,000

10,937

Lori D. Lawley
Options

7/31/2019

7/31/2026

$
1.77

11,624

3,725

Carl W. Langren
RSUs

1/4/2016

N/A

N/A

786

786

Carl W. Langren
Options

3/1/2019

2/28/2029

$
1.80

185,000

40,468

Carl W. Langren
Options

7/31/2019

7/31/2026

$
1.77

157,174

45,775

Bradley J. Powers
Options

8/1/2018

7/31/2028

$
3.17

50,000

29,166

Bradley J. Powers
Options

3/1/2019

2/28/2029

$
1.80

80,000

17,500

Bradley J. Powers
Options

7/31/2019

7/31/2026

$
1.77

17,071

6,216

Chad A. Johnson
Options

5/10/2019

5/09/2029

$
1.69

25,000

25,000

Chad A. Johnson
Options

7/31/2019

7/31/2026

$
1.77

38,052

12,313

Thomas A. Raffin, M.D.
Options

5/10/2019

5/9/2029

$
1.69

25,000

25,000

Thomas A. Raffin, M.D.
Options

7/31/2019

7/31/2026

$
1.77

93,984

46,989

Matthew L. Sherman
Options

5/10/2019

5/9/2029

$
1.69

25,000

25,000

Matthew L. Sherman
Options

7/31/2019

7/31/2026

$
1.77

45,613

45,613

Ernest J. Talarico
Options

5/10/2019

5/9/2029

$
1.69

25,000

25,000

Ernest J. Talarico
Options

7/31/2019

7/31/2026

$
1.77

75,332

75,332

Lota S. Zoth
Options

5/10/2019

5/9/2029

$
1.69

25,000

25,000

Lota S. Zoth
Options

7/31/2019

7/31/2026

$
1.77

47,952

23,974

The foregoing discussion of the interests of the NewLink directors and executive officers in the Merger reflects, with respect to the executive officers, the twelve-month acceleration, and with respect to the resigning directors, 100% acceleration, of the then unvested shares of common stock described above, but does not reflect the effect of the reverse stock split.

Golden Parachute Compensation

The information set forth in this section is intended to comply with Item 402(t) of Regulation S-K regarding the compensation for NewLink's named executive officers based on the Merger. The compensation information for Dr. Link and Dr. Vahanian is not included in the table below as they have both left

their positions at the Company and their benefits granted under their respective separation and transition agreements were not contingent upon or in connection with the Merger. See "—Executive Officer Transitions."

The amounts shown in the table below are estimates based on multiple assumptions that may or may not actually occur or be accurate on the relevant date, including the assumptions described below and in the footnotes to the table, and do not reflect certain compensation actions that may occur before completion of the Merger. For purposes of calculating such amounts, the following assumptions were used:

- the assumed date of the Effective Time is December 31, 2019;
- the value of a share of NewLink's common stock is assumed to be $1.218, which is the average closing price per share of NewLink's common stock over the five business days following the first public announcement of the Merger on September 30, 2019; and
- the employment of each named executive officer of NewLink is terminated by NewLink without "Cause" or by the named executive officer for "Good Reason" in connection with the Merger.

The amounts below do not reflect certain compensation actions that may occur before the Effective Time. The actual amounts payable to NewLink's named executive officers currently in office, if any, will depend on whether the named executive officer incurs a qualifying termination, the date of termination of the named executive officer's employment, the closing date of the Merger, the value of NewLink's common stock on the termination date, the manner of termination, and the terms of the plans or agreements in effect at such time.

Name	Cash(1)	Equity(2)	Perquisites/ benefits(3)	Total
Carl W. Langren	$ 778,050	$ 957	$ 19,750	$ 798,758
Eugene P. Kennedy, M.D.	612,850	1,346	—	614,196
Bradley J. Powers	448,500	—	19,591	468,091

(1) The amounts in this column represent the cash severance amounts to which the named executive officers would be entitled in severance under their respective employment agreements, assuming a qualifying termination following a Change in Control.

Name	Base Salary Cash Severance Payments ($)	Annual Bonus Severance Payment at Target ($)
Carl W. Langren	555,750.00	222,300.00
Eugene P. Kennedy, M.D.	437,750.00	175,100.00
Bradley J. Powers	345,000.00	103,500.00

The cash severance payments are "double trigger" benefits contingent upon a qualifying termination of employment within one month before or 13 months following a Change in Control. Pursuant to his employment agreement, upon a qualifying termination of employment within one month before or 13 months following a change of control, Mr. Langren would be entitled to a lump sum cash severance equal to his then-current base salary for 18 months and a lump sum payment of an amount equal to the most recent bonus paid to Mr. Langren multiplied by 1.5. He would also be entitled to COBRA health coverage at NewLink's expense for up to 18 months and 100% accelerated vesting and a 24-month extension of the exercise period of his outstanding equity awards. Pursuant to their respective Employment Agreements, upon a qualifying termination of employment within one month before or 13 months following a Change in Control, the named executive officers (other than Mr. Langren) will be entitled to cash severance, payable in a lump sum, in an amount equal to 12 months of such executive's then-current base salary and 100% of such executive's target bonus. The executives would also be entitled to reimbursement of COBRA for up to 12 months and 100% accelerated vesting and a 24-month extension of the exercise period of their outstanding equity awards. The foregoing severance amounts are payable subject to such named executive officer's execution and non-revocation of a release of claims and continued compliance with covenants of NewLink's proprietary information and inventions agreement.

(2) The amounts in this column represent the value of unvested RSU awards and in the money options, in each case, vesting or accelerating. These are "double-trigger" benefits, which would accelerate upon a qualifying termination of the named executive officer during the one month prior or 13-month period following the Effective Date.

(3) The amounts in the table include the estimated value of continued health benefits under COBRA for up to 18 months for Mr. Langren and continued health plan participation for up to 12 months for the other executive officers, which, in each case, are "double-trigger" benefits payable following a qualifying termination under each executive officer's respective employment agreement.

Opinion of NewLink's Financial Advisor

The NewLink Board engaged Stifel to act as its financial advisor in connection with the Merger. On September 30, 2019, Stifel delivered to the NewLink Board its oral opinion, subsequently confirmed in writing by delivery of a written opinion dated September 30, 2019, which is referred to herein as the Opinion, that, as of that date, and based upon and subject to the assumptions made, procedures followed, matters considered and qualifications and limitations of review set forth therein, the Merger Consideration to be paid by NewLink in the Merger pursuant to the Merger Agreement was fair to NewLink from a financial point of view.

NewLink did not impose any limitations on Stifel with respect to the investigations made or procedures followed in rendering its Opinion. In selecting Stifel, the NewLink Board considered, among other things, the fact that Stifel is a reputable investment banking firm with substantial experience advising companies in the healthcare and biopharmaceutical sectors and in providing strategic advisory services in general. Stifel, as part of its investment banking business, is regularly engaged in the independent valuation of businesses and securities in connection with mergers, acquisitions, underwritings, sales and distributions of listed and unlisted securities, private placements and valuations for estate, corporate and other purposes. In the ordinary course of business, Stifel, its affiliates and their respective clients may transact in the equity securities of NewLink and may at any time hold a long or short position in such securities.

THE FULL TEXT OF THE WRITTEN OPINION THAT STIFEL DELIVERED TO THE NEWLINK BOARD IS ATTACHED TO THIS PROXY STATEMENT AS ANNEX F AND IS INCORPORATED INTO THIS DOCUMENT BY REFERENCE. THE SUMMARY OF STIFEL'S OPINION SET FORTH IN THIS PROXY STATEMENT IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO THE FULL TEXT OF

THE OPINION. NEWLINK STOCKHOLDERS ARE URGED TO READ THE OPINION CAREFULLY AND IN ITS ENTIRETY FOR A DISCUSSION OF THE ASSUMPTIONS MADE, PROCEDURES FOLLOWED, MATTERS CONSIDERED AND LIMITS OF THE REVIEW UNDERTAKEN BY STIFEL IN CONNECTION WITH SUCH OPINION.

Stifel's Opinion was for the information of, and directed to, the NewLink Board for its information and assistance in connection with its consideration of the financial terms of the Merger. Stifel's Opinion did not constitute a recommendation to the NewLink Board or any other person as to how the NewLink Board or any other person should vote or otherwise act with respect to the Merger or any other matter, or to any stockholder of NewLink or Lumos as to how any such stockholder should vote or act with respect to the Merger or any other matter, including whether or not any NewLink or Lumos stockholder should exercise any dissenters', appraisal or similar rights that may be available to such stockholder. In addition, Stifel's Opinion did not compare the relative merits of the Merger with any other alternative transactions or business strategies which may have been available to NewLink and did not address the underlying business decision of the NewLink Board to proceed with or effect the Merger.

In connection with its Opinion, Stifel, among other things:

(i) Reviewed the financial terms of the Merger contained in the Merger Agreement;

(ii) Discussed the Merger and related matters with NewLink's counsel and reviewed a draft copy of the Merger Agreement, dated September 30, 2019, such draft being the latest draft provided to Stifel;

(iii) Reviewed and analyzed certain internal financial analyses, financial projections, reports and other information concerning NewLink and Lumos prepared by the management of NewLink, including projections for NewLink and Lumos provided by the management of NewLink and reflecting the probabilities of technical success determined by the management of NewLink (the "NewLink Projections" and the "Lumos Projections," respectively), and utilized per instruction of NewLink;

(iv) Reviewed and discussed with NewLink's management certain other publicly available information concerning NewLink and Lumos;

(v) Reviewed certain other non-publicly available information concerning NewLink and held discussions with NewLink's management regarding recent developments;

(vi) Held discussions with NewLink's management, regarding estimates of certain cost savings, operating synergies, merger charges and the pro forma financial impact of the Merger on NewLink;

(vii) Reviewed the reported prices and trading activity of NewLink's common stock;

(viii) Reviewed and analyzed, based on the Lumos Projections, the cash flows generated by Lumos on a stand-alone basis to determine the present value of those discounted cash flows;

(ix) Reviewed and analyzed certain financial terms of the initial public offerings of certain companies that Stifel deemed relevant to Lumos;

(x) Reviewed and analyzed certain publicly available information concerning the terms of selected merger and acquisition transactions that Stifel considered relevant to its analysis;

(xi) Reviewed and analyzed certain publicly available financial and stock market data relating to selected public companies that Stifel deemed relevant to its analysis;

(xii) Participated in certain discussions and negotiations between representatives of NewLink and Lumos;

(xiii) Conducted such other financial studies, analyses and investigations and considered such other information as Stifel deemed necessary or appropriate for purposes of its Opinion; and

(xiv) Took into account Stifel's assessment of general economic, market and financial conditions and its experience in other transactions, as well as its experience in securities valuations and its knowledge of NewLink's industry generally.

In rendering the Opinion, Stifel relied upon and assumed, without independent verification, the accuracy and completeness of all of the financial and other information that was provided to Stifel by or on behalf of NewLink or Lumos, or that was otherwise reviewed by Stifel, and did not assume any responsibility for independently verifying

any of such information. With respect to the financial forecasts supplied to it by NewLink (including, without limitation, the NewLink Projections and Lumos Projections and potential cost savings and operating synergies which may be realized as a result of the Merger), Stifel assumed, at the direction of NewLink, that such forecasts were reasonably prepared on the basis reflecting the best currently available estimates and judgments of the management of NewLink as to the future operating and financial performance of NewLink and Lumos, as applicable, and that they provided a reasonable basis upon which Stifel could form its Opinion. Such forecasts and projections were not prepared with the expectation of public disclosure. All such projected financial information is based on numerous variables and assumptions that are inherently uncertain, including, without limitation, factors related to general economic and competitive conditions. Accordingly, actual results could vary significantly from those set forth in such projected financial information. Stifel relied on this projected financial information without independent verification or analyses and does not in any respect assume any responsibility for the accuracy or completeness thereof. Stifel assumed for purposes of its Opinion, at the direction of NewLink management, that NewLink management will be evaluating its pipeline pending results of the diffuse intrinsic pontine glioma ("DIPG") cohort of its Phase 1b clinical trial for indoximod, and that NewLink management does not intend to pursue further internal development of its existing pipeline and may seek to identify potential partnerships and licensing opportunities. Stifel also assumed for purposes of its Opinion that, as of the date of the Opinion, all out-of-the-money options to purchase shares of NewLink's common stock and all out-of-the-money Lumos options were without value.

Stifel also assumed that there were no material changes in the assets, liabilities, financial condition, results of operations, business or prospects of either NewLink or Lumos since the date of the last financial statements of each company made available to Stifel. Stifel did not make or obtain any independent evaluation, appraisal or physical inspection of either NewLink's or Lumos' assets or liabilities, nor was Stifel furnished with any such evaluation or appraisal. Estimates of values of companies and assets do not purport to be appraisals or necessarily reflect the prices at which companies or assets may actually be sold. Because such estimates are inherently subject to uncertainty, Stifel assumes no responsibility for their accuracy.

Stifel assumed, with NewLink's consent, that there are no factors that would delay or subject to any adverse conditions any necessary regulatory or governmental approval and that all conditions to the Merger will be satisfied and not waived. In addition, Stifel assumed that the definitive Merger Agreement would not differ materially from the draft Stifel reviewed. Stifel also assumed that the Merger will be consummated substantially on the terms and conditions described in the Merger Agreement, without any waiver of material terms or conditions by NewLink or any other party and without any anti-dilution or other adjustment to the Merger Consideration, and that obtaining any necessary regulatory approvals or satisfying any other conditions for consummation of the Merger will not have an adverse effect on NewLink, Lumos or the Merger. Stifel assumed that the Merger will be consummated in a manner that complies with the applicable provisions of the Securities Act, the Exchange Act and all other applicable federal and state statutes, rules and regulations. Stifel further assumed that NewLink relied upon the advice of its counsel, independent accountants and other advisors (other than Stifel) as to all legal, financial reporting, tax, accounting and regulatory matters with respect to NewLink, the Merger and the Merger Agreement.

Stifel's Opinion is limited to whether the Merger Consideration to be paid by NewLink in the Merger pursuant to the Merger Agreement is fair to NewLink, from a financial point of view, and does not address any other terms, aspects or implications of the Merger, including, without limitation, the form or structure of the Merger, any consequences of the Merger on NewLink, its stockholders, creditors or any other constituency or otherwise, or any terms, aspects or implications of any voting, support, stockholder or other agreements, arrangements or understandings contemplated or entered into in connection with the Merger or otherwise. Stifel's Opinion also does not consider, address or include: (i) any other strategic alternatives currently (or which have been or may be) contemplated by the NewLink Board or NewLink; (ii) the legal, tax or accounting consequences of the Merger on NewLink or the holders of NewLink's securities; (iii) the fairness of the amount or nature of any compensation to any of NewLink's officers, directors or employees, or class of such persons, relative to the compensation to the holders of NewLink's securities; (iv) the effect of the Merger on, or the fairness of the consideration to be received by, holders of any class of securities of NewLink, or any class of securities of any other party to any transaction contemplated by the Merger Agreement; or (v) whether NewLink has sufficient cash, available lines of credit or other sources of funds to enable it to pay the cash component of the Merger Consideration. Furthermore, Stifel did not express any opinion as to the prices, trading range or volume at which NewLink's securities would trade following public announcement or consummation of the Merger.

Stifel's Opinion was necessarily based on economic, market, financial and other conditions as they existed on, and on the information made available to it by or on behalf of NewLink or its advisors, or information otherwise reviewed by Stifel, as of the date of the Opinion. It is understood that subsequent developments may affect the conclusion reached in Stifel's Opinion and Stifel does not have any obligation to update, revise or reaffirm its Opinion, except in accordance with the terms and conditions of Stifel's engagement letter agreement with NewLink.

Stifel is not a legal, tax, regulatory or bankruptcy advisor. Stifel has not considered any potential legislative or regulatory changes currently being considered or recently enacted by the United States Congress or the SEC, or any other regulatory bodies, or any changes in accounting methods or generally accepted accounting principles that may be adopted by the SEC or the Financial Accounting Standards Board. Stifel's Opinion is not a solvency opinion and does not in any way address the solvency or financial condition of NewLink or Lumos either before or after the Merger.

Stifel has acted as financial advisor to NewLink in connection with the Merger and will receive an advisory fee for its services, a substantial portion of which is contingent upon the completion of the Merger. Stifel has also acted as a financial advisor to the NewLink Board and will receive a fee upon the delivery of this Opinion, which is not contingent upon consummation of the Merger, but which is creditable against any advisory fee. Stifel will not receive any other significant payment or compensation contingent upon the successful consummation of the Merger. In addition, NewLink has agreed to reimburse certain of Stifel's expenses and indemnify Stifel for certain liabilities arising out of Stifel's engagement. In October 2017, Stifel acted as joint book-running manager for NewLink's offering of 5,750,000 shares of common stock for which Stifel was paid customary fees. Other than this offering, there are no material relationships that existed during the two years prior to the date of Stifel's Opinion or that are mutually understood to be contemplated in which any compensation was received or is intended to be received as a result of the relationship between Stifel and any party to the Merger. Stifel may seek to provide investment banking services to NewLink or its affiliates (including Lumos) in the future, for which Stifel would seek customary compensation.

Stifel's Fairness Opinion Committee approved the issuance of the Opinion. Stifel's Opinion may not be published or otherwise used or referred to, nor shall any public reference to Stifel be made, without Stifel's prior written consent, except in accordance with the terms and conditions of Stifel's engagement letter agreement with NewLink.

In accordance with customary investment banking practice, Stifel employed generally accepted valuation methods and financial analyses in reaching its Opinion. The following is a brief summary of the material financial analyses performed by Stifel in arriving at its Opinion. These summaries of financial analyses alone do not constitute a complete description of the financial analyses Stifel employed in reaching its conclusions. None of the analyses performed by Stifel were assigned a greater significance by Stifel than any other, nor does the order of analyses described represent relative importance or weight given to those analyses by Stifel. The financial analyses summarized below include information presented in tabular format. In order to fully understand the financial analyses used by Stifel, the tables must be read together with the text of each summary. The tables alone do not constitute a complete description of the financial analyses. The summary text describing each financial analysis does not constitute a complete description of Stifel's financial analyses, including the methodologies and assumptions underlying the analyses, and if viewed in isolation could create a misleading or incomplete view of the financial analyses performed by Stifel. The summary text set forth below does not represent and should not be viewed by anyone as constituting conclusions reached by Stifel with respect to any of the analyses performed by it in connection with its Opinion. Rather, Stifel made its determination as to the fairness, from a financial point of view, to NewLink of the Merger Consideration to be paid by NewLink in the Merger pursuant to the Merger Agreement on the basis of its experience and professional judgment after considering the results of all of the analyses performed.

Except as otherwise noted, the information utilized by Stifel in its analyses, to the extent based on market data, was based on market data as it existed on or before September 30, 2019 and is not necessarily indicative of current market conditions. The analyses described below do not purport to be indicative of actual future results, or to reflect the prices at which any securities may trade in the public markets, which may vary depending upon various factors, including changes in interest rates, dividend rates, market conditions, economic conditions and other factors that influence the price of securities.

In connection with its Opinion, Stifel conducted an analysis of the ratios of the pre-Merger stand-alone equity value of NewLink relative to the pre-Merger stand-alone equity value of Lumos, in each case as implied by valuation

analyses conducted by Stifel and described below. In conducting its analysis, Stifel used six primary methodologies: in the case of NewLink, Company Cash Analysis and Selected Precedent Priority Review Voucher ("PRV") transactions analysis; and, in the case of Lumos, selected publicly traded companies analysis; selected precedent transactions analysis; discounted cash flow ("DCF") analysis; and selected precedent initial public offering ("IPO") analysis.

NewLink:

Stifel noted that, based upon the NewLink Projections, upon closing of the Merger and assuming a closing date of December 31, 2019, NewLink will have estimated cash and cash equivalents on hand of approximately $89.5 million. Because NewLink management informed Stifel that NewLink management will be evaluating its pipeline pending results of the DIPG cohort of its Phase 1b clinical trial for indoximod, and that NewLink management does not intend to pursue further internal development of its existing pipeline and may seek to identify potential partnerships and licensing opportunities, Stifel used this amount in determining the implied equity value of NewLink as of the closing of the Merger as noted below. As directed by NewLink management, in determining the implied equity value of NewLink, Stifel analyzed the expected value to NewLink of the PRV that would be issuable to Merck if Merck's BLA for the licensed Ebola vaccine is approved by the FDA but Stifel did not otherwise attribute any value to future royalties or any other amounts that NewLink would be entitled to receive under the Merck Agreement.

Selected Precedent PRV Transactions Analysis

Stifel reviewed certain publicly available information for the following 17 PRV sale transactions, announced subsequent to July 1, 2014:

Selected Precedent PRV Transactions

Date	**Target**	**Acquirer**	**Purchase Price (in $mm)**
08/22/19	Sobi	AstraZeneca	95.0
08/09/19	Medicines Development for Global Health	Novo Nordisk	Not Disclosed
03/18/19	GW Pharmaceutical	Biohaven	105.0
11/02/18	Siga Technologies	Eli Lilly	80.0
June 2018	Ultragenyx and Kyowa	Not Disclosed	80.6
05/01/18	Spark Therapeutics	Jazz Pharmaceuticals	110.0
2017	Anonymous	ViiV	130.0
12/18/17	Ultragenyx		

Novartis

130.0

11/27/18
BioMarin
Not Disclosed

125.0

10/17/17
Not Disclosed
Teva

150.0

02/21/17
Sarepta
Gilead

125.0

06/10/16
PaxVax Bermuda
Gilead

338.0

09/04/15
Wellstat
AstraZeneca
Not Disclosed
08/19/15
United Therapeutics
AbbVie

350.0

05/27/15
Retrophin
Sanofi

245.0

11/19/14
Knight
Gilead

125.0

07/30/14
BioMarin
Regeneron and Sanofi

67.5

For each of the selected transactions, Stifel analyzed transaction value as obtained from publicly available sources. The first and third quartile transaction value calculated for the six selected precedent PRV transactions since 2018 are shown in the table below:

Transaction Value of Selected Precedent PRV Transactions	
First Quartile	$80.6 million
Third Quartile	$105.0 million

Based on the first and third quartile transaction values of the selected precedent PRV transactions, Stifel calculated a range of estimated values after adjusting for amounts due to Merck and Public Health Agency of Canada upon sale of the PRV and its estimated tax impact, a probability of success of 90.35% provided by NewLink management and a discount rate of 8.0% to reflect the time value of money, costs and risk associated with monetization. This analysis resulted in the following range of estimated PRV values for NewLink:

Estimated Value of NewLink PRV

Low	$36.5 million
High	$47.5 million

Stifel calculated a range of total implied equity values for NewLink by adding estimated cash and cash equivalents for NewLink at closing of the Merger of $89.5 million to the estimated PRV values for NewLink reflected in the above table. This analysis resulted in the following range of implied equity values for NewLink:

NewLink Implied Equity Value

Low	$126.0 million
High	$137.0 million

Lumos:

Selected Publicly Traded Companies Analysis

Stifel compared Lumos, from a financial point of view, to 13 selected publicly traded companies in the orphan disease space whose lead value generating asset was in Phase 2 of development, excluding oncology and gene therapy companies, which Stifel deemed to be relevant based on their business profiles and financial metrics, including product portfolios, end-markets, customers, size, growth and profitability, among others. Stifel compared Lumos' estimated calendar year 2019 financial metrics, as provided by NewLink's management, to estimated calendar year 2019 financial metrics of these 13 selected companies, obtained from available public sources. Stifel believes that the groups of companies listed below have business models similar to those of Lumos, but noted that none of these companies has the same management, composition, size, operations, financial profile or combination of businesses as Lumos. Accordingly, this analysis is not purely mathematical, but also involves complex considerations and judgments concerning the differences in financial and operating characteristics of the selected companies and other factors.

The following table lists the equity and enterprise values of each of the 13 selected publicly traded companies.

Selected Publicly Traded Companies

Company	Equity Value (in $mm)	Enterprise Value (in $mm)
Dicerna Pharmaceuticals, Inc.	$ 1,064.2	$ 714.0
Wave Life Sciences Ltd.	723.4	470.5
Translate Bio, Inc.	603.7	372.6
Crinetics Pharmaceuticals Inc.	368.8	223.8
Scholar Rock Holding Corp.	284.1	

98.9

ProQR Therapeutics N.V.

244.0

165.3

Fulcrum Therapeutics, Inc.

218.0

333.5

KalVista Pharmaceuticals, Inc.

209.7

108.9

PhaseBio Pharmaceuticals, Inc.

132.2

51.5

Verona Pharma plc

88.0

30.7

Equillium, Inc.

64.8

7.9

Akari Therapeutics Plc

35.1

32.3

Entera Bio Ltd.

30.0

22.7

For each of the selected companies, Stifel calculated an enterprise value (calculated as equity value based on closing stock prices on September 27, 2019 plus total debt less cash and equivalents, as obtained from publicly available sources). The first and third quartile enterprise values calculated for the selected companies are shown in the table below:

Enterprise Value of Selected Publicly Traded Companies	
First Quartile	$32.3 million
Third Quartile	$333.5 million

Based on the first and third quartile enterprise values of the selected companies, Stifel calculated a range of implied equity values for Lumos by adding to such enterprise values Lumos' net cash, which Stifel defined as estimated cash and cash equivalents less total debt at the closing of the Merger, as provided by NewLink management. This analysis resulted in the following range of implied equity values for Lumos:

Lumos Implied Equity Value	
Low	$37.5 million
High	$338.7 million

Stifel then calculated the range of implied ownership percentages for NewLink stockholders after giving effect to the Merger by comparing the low implied equity value of NewLink and the high implied equity value of Lumos, and the high implied equity value of NewLink and the low implied equity value of Lumos, based upon the analyses set forth above. The following table reflects the results of this analysis:

NewLink Implied Ownership Percentages	
Low	27.1%
High	78.5%

Stifel noted that the ownership percentage of NewLink stockholders in the combined company implied by the Merger was within the range of ownership percentages implied by this analysis.

Selected Precedent Transactions Analysis

Stifel reviewed certain publicly available information for the following ten business combinations of biotechnology companies, announced subsequent to January 1, 2011 involving targets whose lead value generating asset was in an orphan indication and was in Phase 2 of development at the time of the acquisition, excluding oncology and gene therapy companies:

Selected Precedent Transactions

Date	Target	Acquirer	Equity Value (in $mm)	Enterprise Value (in $mm)
07/19/19	Cynata Therapeutics	Sumitomo Dainippon Pharma	$ 146.2	$ 141.3
12/27/16	Essentialis	Capnia	14.1	14.1
06/09/16	Afferent Pharmaceuticals	Merck & Co.	500.0	500.0
11/09/15	Ocata Therapeutics	Astellas Pharma.	362.5	336.4
05/15/15	Aspireo Pharma	Cortendo AB	30.0	30.0
03/04/15	SuppreMol GmbH	Baxter International	223.7	223.7
01/11/15	Convergence Pharmaceuticals	Biogen Idec	200.0	200.0
05/12/14	Lumena Pharmaceuticals	Shire plc	260.0	260.0
12/28/11	Enobia Pharma	Alexion Pharmaceuticals	610.0	610.0
06/13/11	Synageva BioPharma	Trimeris, Inc.	206.6	191.9

No transaction used in the precedent transactions analyses is identical to the Merger. Accordingly, an analysis of the results of the foregoing is not mathematical; rather, it involves complex considerations and judgments concerning differences in financial and operating characteristics of the companies and other factors that could affect the public trading value of the companies involved in the precedent transactions which, in turn, could affect the enterprise values and equity values of the companies involved in the transactions to which the Merger is being compared. In evaluating the precedent transactions, Stifel made judgments and assumptions with regard to industry performance, general business, economic, market and financial conditions and other matters, such as the impact of competition, industry growth and the absence of any adverse material change in the financial condition of NewLink or the companies involved in the precedent transactions or the industry or in the financial markets in general, which could affect the public trading value of the companies involved in the selected transactions which, in turn, could affect the enterprise values and equity values of the companies involved in the transactions to which the Merger is being compared.

For each of the selected transactions, Stifel calculated an enterprise value (calculated as equity value based on the purchase consideration at announcement plus total debt less cash and cash equivalents, excluding contingent payments) as obtained from publicly available sources. The first and third quartile enterprise values calculated for the selected precedent transactions are shown in the table below:

Enterprise Value of Selected Precedent Transactions	
First Quartile	$153.9 million
Third Quartile	$317.3 million

Based on the first and third quartile enterprise values of the selected precedent transactions, Stifel calculated a range of implied equity values for Lumos by adding to such enterprise values Lumos' net cash, which Stifel defined as estimated cash and cash equivalents less total debt at the closing of the Merger, as provided by NewLink management. This analysis resulted in the following range of implied equity values for Lumos:

Lumos Implied Equity Value	
Low	$159.1 million
High	$322.5 million

Stifel then calculated the range of implied ownership percentages for NewLink stockholders after giving effect to the Merger by comparing the low implied equity value of NewLink, and the high implied equity value of Lumos, and the high implied equity value of NewLink and the low implied equity value of Lumos, based upon the analyses set forth above. The following table reflects the results of this analysis:

NewLink Implied Ownership Percentages	
Low	28.1%
High	46.3%

Stifel noted that the ownership percentage of NewLink stockholders in the combined company implied by the Merger was above the range of ownership percentages implied by this analysis.

Selected Precedent Initial Public Offerings Analysis

Stifel reviewed certain publicly available information for the following 17 initial public offerings for biotechnology companies announced subsequent to January 1, 2013, involving selected orphan disease companies with products in either Phase 2, Phase 2/3, or Phase 2 Ready stage of development:

Selected Precedent Initial Public Offerings

Date	Company	Issuance Amount (in $mm)	Pre-Money Value (in $mm)	Post-Money Value (in $mm)
07/17/19	Fulcrum Therapeutics	$ 72.0	$ 314.5	$ 386.5
10/17/18	PhaseBio Pharmaceuticals	46.0	77.0	123.0
10/11/18	Equillium	65.4	170.7	236.0
07/18/18	Allakos	128.4	717.4	845.8
07/17/18	Crinetics Pharmaceuticals	102.0	319.4	421.4
06/27/18	Entera Bio	11.2	105.9	117.1
06/27/18	Translate Bio	121.6	492.7	614.3
04/26/17	Verona Pharma	80.0	87.1	167.1
08/04/16	Gemphire Therapeutics	30.0	56.6	86.6
08/12/15	Global Blood Therapeutics	120.0	483.0	603.0
06/24/15	Catabasis	60.0	124.6	184.6
05/06/15	Atyr Pharma	75.0	258.0	333.0
03/05/15	Summit Therapeutics	34.2	81.4	115.6
01/27/15	Ascendis Pharma	108.0	338.1	446.1
07/30/14	Bio Blast Pharma	35.2	122.8	158.0
07/17/14	Sage Therapeutics	90.0	360.1	450.1
07/25/13	Conatus Pharmaceuticals	66.0	111.1	177.1

Stifel selected the initial public offerings on the basis of various factors, including the size of the companies, the current phase of the companies' life cycles and the similarity of the lines of business, although no company used in this analysis is identical to Lumos. Accordingly, this analysis is not purely mathematical, but also involves complex considerations and judgments concerning the differences in financial and operating characteristics of the selected companies and other factors.

For each of the selected precedent initial public offerings, Stifel calculated a pre-money equity value based on the pricing of their respective initial public offerings. The first and third quartile pre-money equity values calculated for the selected precedent initial public offerings are shown in the table below:

Equity Value of Selected Precedent Initial Public Offerings

First Quartile	$105.9 million
Third Quartile	$338.1 million

Stifel then calculated the range of implied ownership percentages for NewLink stockholders after giving effect to the Merger by comparing the low implied equity value of NewLink and the high implied equity value of Lumos, and the high implied equity value of NewLink and the low implied equity value of Lumos. The following table reflects the results of this analysis:

NewLink Implied Ownership Percentages

Low	27.1%
High	56.4%

Stifel noted that the ownership percentage of NewLink stockholders in the combined company implied by the Merger was within the range of ownership percentages implied by this analysis.

Discounted Cash Flow Analysis

Stifel used the Lumos Projections, as provided by NewLink management, to perform a discounted cash flow analysis of Lumos on a stand-alone basis. Stifel calculated the terminal value of the projected unlevered free cash flow by applying a range of perpetuity growth rates of (90.0%) to (70.0%) in 2036 to reflect patent expiry and entry of generics that would materially adversely impact sales and profitability, as instructed by NewLink management and based on Stifel's professional judgement. Stifel then discounted these cash flows to present values using discount ranges from 13.5% to 15.5%, based on Lumos' weighted average cost of capital, considering Lumos' company- specific circumstances and Stifel's business and industry knowledge. This analysis yielded a range of enterprise values for Lumos from which Stifel calculated a range of implied equity values for Lumos by adding to such enterprise values Lumos' net cash, which Stifel defined as estimated cash and cash equivalents less total debt at the closing of the Merger, as provided by NewLink management. This analysis resulted in the following range of implied equity values for Lumos:

Lumos Implied Equity Value

Low	$105.4 million
High	$148.2 million

Stifel then calculated the range of implied ownership percentages for NewLink stockholders after giving effect to the Merger by comparing the low implied equity value of NewLink and the high implied equity value of Lumos, and the high implied equity value of NewLink and the low implied equity value of Lumos. The following table reflects the results of this analysis:

NewLink Implied Ownership Percentages

Low	45.9%
High	56.5%

Stifel noted that the ownership percentage of NewLink stockholders in the combined company implied by the Merger was within the range of ownership percentages implied by this analysis.

Subsequent to the delivery of Stifel's opinion, NewLink's management discovered that, as a result of a previous amendment to the agreement between NewLink and the Public Health Agency of Canada that management inadvertently did not provide to Stifel, NewLink is not required to make a payment to the Public Health Agency of

Canada in connection with the sale of the PRV. Upon discovery of this omission, management of NewLink consulted with Stifel regarding the impact, if any, that this information would have had on Stifel's opinion had Stifel been in possession of such information at the time it rendered its opinion. Based upon this additional information, Stifel calculated that, as of the date of its opinion, and based upon the valuation methodology employed by Stifel to value the PRV, the implied equity value of NewLink would be between $3.1 million and $4.4 million higher, or between approximately 2.5% and 3.2% higher, respectively. Stifel indicated that, had it been in possession of such information at the time it rendered its opinion, subject to the assumptions, qualifications and limitations set forth in the opinion, it would have reached the same conclusion. Stifel was not asked to update or reaffirm its opinion to account for any subsequent events occurring after the date of its opinion.

Miscellaneous

No individual methodology was given a specific weight, nor should any methodology be viewed individually. Additionally, no company or transaction used in any analysis as a comparison is identical to NewLink or Lumos or the Merger, and they all differ in material ways. Accordingly, an analysis of the results described above is not mathematical; rather it involves complex considerations and judgments concerning differences in financial and operating characteristics of the companies and other factors that could affect the public trading value of the selected companies, transactions or offerings to which they are being compared.

The preparation of a fairness opinion is a complex process and is not necessarily susceptible to a partial analysis or summary description. In arriving at its Opinion, Stifel considered the results of all of its analyses as a whole and did not attribute any particular weight to any analysis or factor considered by it. Stifel believes that the summary provided and the analyses described above must be considered as a whole and that selecting portions of these analyses, without considering all of them, would create an incomplete view of the process underlying Stifel's analyses and Opinion; therefore, the ranges of valuations and relative valuations resulting from any particular analysis described above should not be taken to be Stifel's view of the actual valuation of either NewLink or Lumos or their relative valuations.

Stifel is acting as financial advisor to NewLink in connection with the Merger. NewLink agreed to pay Stifel a fee of $1,750,000 for its services, $750,000 of which became payable upon the delivery of Stifel's Opinion, and the remaining portion of which is contingent upon the closing of the Merger. In addition, NewLink has agreed to reimburse Stifel for its expenses incurred in connection with Stifel's engagement and to indemnify Stifel and its affiliates and their respective officers, directors, employees and agents, and any persons controlling Stifel or any of its affiliates, against specified liabilities.

Certain NewLink and Lumos Unaudited Prospective Financial and Operating Information

Neither NewLink nor Lumos, as a matter of course, makes public long-term forecasts or projections as to future performance, revenues, production, earnings or other results due to, among other reasons, the uncertainty of the underlying assumptions and estimates. However, in connection with the NewLink Board's evaluation of the Merger, NewLink's management prepared certain unaudited prospective internal financial projections with respect to NewLink that were provided to the NewLink Board in connection with its evaluation of the Merger and to Stifel in connection with its preparation of its fairness opinion (such projections are referred to hereinafter and in "— Opinion of NewLink's Financial Advisor" as the NewLink Projections). In addition, NewLink received from Lumos certain unaudited internal financial projections with respect to Lumos, which Lumos management provided for use by NewLink. These Lumos Projections, as provided by Lumos and as reviewed and adjusted by NewLink's management, were also provided to the NewLink Board in connection with its evaluation of the Merger and to Stifel in connection with its preparation of its fairness opinion (such projections, as reviewed and adjusted by NewLink's management, are referred to hereinafter and in "— Opinion of NewLink's Financial Advisor" as the Lumos Projections). The NewLink Projections and Lumos Projections included below are hereinafter referred to as the projections. The inclusion of the projections should not be regarded as an indication that any of NewLink, Lumos, or their respective advisors or other representatives or any other recipient of the projections considered, or now considers, it to be necessarily predictive of actual future performance or events, or that it should be construed as financial guidance, and such summary projections set forth below should not be relied on as such.

The projections were prepared solely for internal use and are subjective in many respects. While presented with numeric specificity, the projections reflect numerous estimates and assumptions that are inherently uncertain and may be beyond the control of NewLink's or Lumos' management, including the matters described in "Cautionary Statement Regarding Forward-Looking Statements" and "Risk Factors." The projections reflect both assumptions as

to certain business decisions that are subject to change and, in many respects, subjective judgment, and thus are susceptible to multiple interpretations and periodic revisions based on actual experience and business developments. NewLink and Lumos can give no assurance that the projections and the underlying estimates and assumptions will be realized. In addition, since the Lumos Projections cover multiple years, such information by its nature becomes less predictive with each successive year. Actual results may differ materially from those set forth below, and important factors that may affect actual results and cause the projections to be inaccurate include, but are not limited to, risks and uncertainties relating to the companies' businesses, industry performance, the regulatory environment, general business and economic conditions and other matters described under the section of this proxy statement titled "Risk Factors." See also "Cautionary Statement Regarding Forward-Looking Statements" and "Where You Can Find More Information."

The projections were not prepared with a view toward public disclosure, nor were they prepared with a view toward compliance with GAAP, published guidelines of the SEC or the guidelines established by the American Institute of Certified Public Accountants for preparation and presentation of prospective financial information. Neither NewLink's nor Lumos' independent registered public accounting firm, nor any other independent accountants, has compiled, examined or performed any procedures with respect to the projections contained herein, nor have they expressed any opinion or any other form of assurance on such information or its achievability. The report of the independent registered public accounting firm to NewLink contained in its Annual Report on Form 10-K for the year ended December 31, 2018, which is incorporated by reference into this proxy statement, relates to historical financial information of NewLink, and such report does not extend to the projections included below and should not be read to do so.

Furthermore, the projections do not take into account any circumstances or events occurring after the date they were prepared. NewLink and Lumos can give no assurance that, had the projections been prepared either as of the date of the Merger Agreement or as of the date of this proxy statement, similar estimates and assumptions would be used. Except as required by applicable securities laws, NewLink and Lumos do not intend to, and disclaim any obligation to, make publicly available any update or other revision to the projections to reflect circumstances existing since their preparation or to reflect the occurrence of unanticipated events, even if any or all of the underlying assumptions are shown to be in error or to reflect changes in general economic or industry conditions. The projections do not take into account the possible financial and other effects on NewLink or Lumos of the Merger, the effect on NewLink or Lumos of any business or strategic decision or action that has been or will be taken as a result of the Merger Agreement having been executed, or the effect of any business or strategic decisions or actions that would likely have been taken if the Merger Agreement had not been executed, but which were instead altered, accelerated, postponed or not taken in anticipation of the Merger. Further, the projections do not take into account the effect on NewLink or Lumos of any possible failure of the Merger to occur. None of NewLink, Lumos, or their respective affiliates, officers, directors, advisors or other representatives has made, makes or is authorized in the future to make any representation to any NewLink stockholder or other person regarding NewLink's or Lumos' ultimate performance compared to the information contained in the projections or that the forecasted results will be achieved. The inclusion of the projections herein should not be deemed an admission or representation by NewLink, Lumos, their respective advisors or any other person that they are viewed as material information of NewLink or Lumos, particularly in light of the inherent risks and uncertainties associated with such forecasts. The summary of the projections included below is not being included to influence your decision whether to vote in favor of or against any proposal to be considered at the Special Meeting, but is being provided solely because the projections were made available to the NewLink Board and Stifel in connection with the Merger.

In light of the foregoing, and considering that the Special Meeting will be held several months after the projections were prepared, as well as the uncertainties inherent in any forecasted or projected information, NewLink stockholders are cautioned not to place undue reliance on such information, and NewLink urges you to review our most recent SEC filings for a description of our reported financial results and Lumos' audited and unaudited financial results included herein. See "Where You Can Find More Information."

Each of the NewLink Projections and the Lumos Projections were prepared in September 2019 and provided to Stifel on September 23, 2019. A summary of the NewLink Projections and the Lumos Projections is set forth below.

In light of the foregoing factors and the uncertainties inherent in financial projections, stockholders are cautioned not to place undue reliance, if any, on the NewLink Projections or the Lumos Projections.

NewLink Projections

The NewLink Projections provided to the NewLink Board and Stifel consisted of a condensed, projected NewLink standalone balance sheet at December 31, 2019 that indicated NewLink would have $89.5 million of cash and cash equivalents at December 31, 2019 and the amount of cash and cash equivalents did not include any proceeds to be received by NewLink upon sale of the PRV. The NewLink Projections provided to the NewLink Board and Stifel also included assumptions of NewLink management that there was a 90.35% probability that the biologics license application ("BLA") supporting the PRV would receive regulatory approval and that the PRV would be monetized at the end of 2020.

On December 20, 2019, Merck announced that the FDA has approved its application for ERVEBO® (Ebola Zaire Vaccine, Live) for the prevention of disease caused by Zaire ebolavirus in individuals 18 years of age and older. On January 3, 2019, Merck notified NewLink that a PRV has been issued to Merck. Under the terms of the Merck Agreement, upon NewLink's written request, Merck will transfer all of its rights and interests in connection with the PRV to NewLink, and NewLink is entitled to 60% of the value of the PRV obtained through sale, transfer or other disposition of the PRV. No additional milestone payments are due to NewLink under the Merck Agreement as a result of the approval of ERVEBO.

The NewLink Projections and, at NewLink's direction, Stifel's financial analysis did not assume that NewLink would receive any future royalty payments in respect of ERVEBO (or any other royalty-bearing products). The Merck Agreement excludes from the royalty obligation sales of ERVEBO (or any other royalty-bearing products) in Africa and certain Global Alliance for Vaccines and Immunization eligible countries and sales or transfers of ERVEBO (or any other royalty-bearing products) at low or no margin, for charitable purposes or as donations. NewLink believes that the market for the Ebola vaccine will be limited primarily to areas in the developing world that are within the excluded territories or where the Ebola vaccine is donated or sold at low or no margin and therefore NewLink does not expect to receive material royalties under the Merck Agreement in the foreseeable future. To NewLink's knowledge, no other product candidates that that have the potential to become royalty-bearing products under the Merck Agreement are currently under development by Merck.

Lumos Projections

The Lumos Projections provided to the NewLink Board and Stifel consisted of (i) a condensed, projected Lumos standalone balance sheet at December 31, 2019 that indicated Lumos would have $5.2 million of cash and cash equivalents and no debt at December 31, 2019 and (ii) Lumos financial projections for the years ended December 31, 2020 through 2036. The Lumos Projections set forth below for the years ended December 31, 2020 through 2036 include earnings before interest, taxes, depreciation and amortization (EBITDA), which is a non-GAAP measure, and unlevered free cash flow, which is a non-GAAP measure and calculated from EBITDA less taxes, less capital expenditures, and plus or minus, as applicable, net changes in working capital. The Lumos Projections were based on certain internal assumptions about the probability of success through approval, epidemiology, pricing, sales ramp, market growth, market share, competition, timing for clinical trial completion, and commercial launch, as well as estimated tax assets and rates, changes in net working capital, capital expenditures, depreciation and amortization. The probability of technical success attributed to the global indications pursued for the Lumos product candidate LUM-201 in the forecasts are based on management assumptions as well as typical success rates for programs based on similar stages of clinical development and other considerations.

($ in millions)

For the Fiscal Year Ended December 31,
2020E
2021E
2022E
2023E
2024E
2025E
2026E
2027E
2028E
2029E
2030E
2031E
2032E
2033E
2034E
2035E
2036E
Total Revenue
—
—
—

—

—

—

$
8.1

$
21.0

$
34.9

$
101.0

$
171.1

$
245.3

$
257.5

$
265.8

$
274.3

$
283.2

$
292.5

EBITDA
$
(13.5
)
$
(15.6
)
$
(10.0
)
$
(13.6
)
$
(17.9
)
$
(7.5
)
$
(12.9
)
$
1.5

$

14.7

$
70.1

$
130.5

$
194.4

$
204.2

$
210.5

$
217.1

$
223.8

$
230.8

Unlevered Free Cash Flow
$
(13.5
)
$
(15.6
)
$
(10.0
)
$
(13.6
)
$
(17.9
)
$
(7.5
)
$
(15.0
)
$
(1.9
)
$
10.4

$
49.8

$
85.4

$
126.4

$
149.1

$
154.8

$
159.6

$
164.6

$
169.7

The projections indicated NewLink and Lumos would collectively have $94.7 million of cash and cash equivalents at December 31, 2019. After excluding expected restructuring and severance costs, transaction costs and potential employee bonuses, which will not be fully paid out as of December 31, 2019, NewLink management subsequently estimated that the combined company would have approximately $80 million of cash and cash equivalents on a pro forma basis as of December 31, 2019, after providing for restructuring and severance costs and reserves, transaction costs and potential employee bonuses which may not be fully paid out as of December 31, 2019, to pursue clinical development and support ongoing operations of the combined company.

Lumos' Reasons for the Merger

The following discussion sets forth material factors considered by the board of directors of Lumos (the "Lumos Board") in reaching its determination to approve the terms and authorize the execution of the Merger Agreement for the purpose of effecting the Merger; however, it does not include all of the factors considered by the Lumos Board. In light of the number and wide variety of factors considered in connection with its evaluation of the Merger Agreement, the Lumos Board did not consider it practicable to, and did not attempt to, quantify or otherwise assign relative weights to the specific factors it considered in reaching its determination. The Lumos Board viewed its position and determinations as being based on all of the information available and the factors presented to and considered by it. In addition, individual directors may have given different weight to different factors.

In the course of reaching its decision to approve the terms and authorize the execution of the Merger Agreement for the purpose of effecting the Merger, the Lumos Board consulted with Lumos' senior management and legal counsel, reviewed a significant amount of information and considered a number of factors, including, among others:

- historical and current information concerning Lumos' business, including its financial performance and condition, operations, management and competitive position;
- Lumos' prospects if it were to remain an independent company, including its need to obtain additional financing and the potential terms on which it would be able to obtain such financing, if at all;
- the cash resources of the combined company expected to be available at the closing and the anticipated cash burn rate of the combined company;
- the expected broader range of investors to support the development of Lumos' sole product candidate than it could otherwise obtain if it continued to operate as a privately held company;
- the potential to provide its current stockholders with liquidity by owning stock in a public company;
- the expectation that the Merger with NewLink would be a more time- and cost-effective means to access capital than other alternatives;
- the expectation that substantially all of Lumos' employees, particularly its management, will serve in similar roles at the combined company; and
- the terms and conditions of the Merger Agreement, including, without limitation, the following:
    - the expected relative percentage ownership of NewLink securityholders and Lumos securityholders in the combined company initially at the Effective Time and the implied valuation of Lumos based on NewLink's cash contribution to the combined company;
    - the parties' representations, warranties and covenants and the conditions to their respective obligations;
    - the limited number and nature of the conditions of the obligation of NewLink to consummate the Merger; and
    - the likelihood that the Merger will be consummated on a timely basis.

The Lumos Board also considered a number of uncertainties and risks in its deliberations concerning the Merger and the other transactions contemplated by the Merger Agreement, including the following:

- the risk that the potential benefits of the Merger may not be realized;
- the risk that future sales of common stock by existing NewLink stockholders may cause the price of NewLink's common stock to fall, thus reducing the value of the consideration received by Lumos stockholders in the Merger;
- the termination fee of $2.0 million payable by Lumos to NewLink upon the occurrence of certain events, and the potential effect of such termination fee in deterring other potential acquirers from proposing a competing transaction that may be more advantageous to NewLink stockholders;
- the price volatility of NewLink's common stock, which may reduce the value of NewLink's common stock that Lumos stockholders will receive at the Effective Time;
- the potential reduction of NewLink's cash balances prior to closing of the Merger;

- the possibility that NewLink could under certain circumstances consider unsolicited acquisition proposals and terminate the Merger Agreement;
- the possibility that the Merger might not be completed for a variety of reasons, such as the failure of NewLink to obtain the required stockholder vote, and the potential adverse effect on the reputation of Lumos and the ability of Lumos to obtain financing in the future in the event the Merger is not completed;
- the amount of ongoing litigation at NewLink and the likelihood that these matters would still be outstanding following the Merger;
- the risk that the Merger might not be consummated in a timely manner or at all;
- the legal and other expenses to be incurred in connection with the Merger and related administrative challenges associated with combining the organizations;
- the additional accounting, administrative and legal expenses that Lumos' business will be subject to as a public company following the closing to which it has not previously been subject; and
- various other risks associated with the combined company and the Merger, including the risks described in the section titled "Risk Factors" beginning on page 17.

The Lumos Board weighed the benefits, advantages and opportunities of the Merger against the uncertainties and risks described above, as well as the possible diversion of management attention for an extended period of time. After taking into account these and other factors, the Lumos Board approved the terms and authorized execution of the Merger Agreement for the purpose of effecting the Merger.

Interests of Lumos Directors and Executive Officers in the Merger

Certain members of the Lumos Board and executive officers of Lumos have interests in the Merger that may be different from, or in addition to, interests they have as Lumos stockholders. All of Lumos' executive officers and its employee directors have options, subject to vesting, to purchase shares of Lumos capital stock that will be assumed by NewLink and converted into and become options to purchase shares of NewLink's common stock. Certain of Lumos' directors and executive officers are expected to become directors and executive officers of the combined company upon the closing and all of Lumos' directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement.

Ownership Interests

Certain of Lumos' directors and executive officers currently hold shares of Lumos capital stock. The table below sets forth the anticipated ownership of Lumos capital stock by Lumos' directors and executive officers immediately prior to the closing based on their ownership of Lumos' capital stock as of December 31, 2019 after giving effect to the applicable exchange ratios.

Directors and Executive Officers	Numbers of Shares of Lumos Capital Stock Held Immediately Prior to the Closing
Cameron Wheeler	—
Carole Nuechterlein	—
Ed Mathers	—
Kevin Lalande	—
Jon S. Saxe	2,532,102
Emmett T. Cunningham, Jr.	—
Robert Heft	—
Richard J. Hawkins	6,477,472
John C. McKew, Ph.D.	—

Certain Lumos stockholders affiliated with Lumos' directors also currently hold shares of Lumos capital stock. The table below sets forth the anticipated ownership of Lumos capital stock by affiliates of Lumos' directors immediately prior to the closing of the Merger based on their ownership of Lumos capital stock as of December 31, 2019 after giving effect to the exchange ratio applicable to exchanging shares of Lumos Series A Preferred Stock for

NewLink's common stock ("Series A Exchange Ratio") and the exchange ratio applicable to exchanging shares of Lumos Series B Preferred Stock for NewLink's common stock ("Series B Exchange Ratio").

Affiliated Entities	Numbers of Shares of Lumos Capital Stock Held Immediately Prior to the Closing
Santé Health Ventures II, L.P.	3,687,381
Deerfield Private Design Fund III, L.P.	8,428,303
Clarus Lifesciences III, L.P.	4,214,150
Entities affiliated with New Enterprise Associates 14, Limited Partnership	4,740,918 (1)
Roche Finance Ltd.	2,633,843

(1) Consists of (i) 23,704 shares held by NEA Ventures 2013, L.P. and (ii) 4,717,214 shares held by New Enterprise Associates 14, L.P.

Treatment of Lumos Stock Options

Under the Merger Agreement, at the Effective Time, each Lumos option outstanding and unexercised as of immediately prior to the Effective Time, whether or not vested, shall be assumed by NewLink and converted into and become an option to purchase that number of shares of NewLink's common stock equal to the product obtained by multiplying (i) the number of shares of Lumos common stock that were subject to such Lumos option immediately prior to the Effective Time by (ii) the Common Stock Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of NewLink's common stock.

The following table presents certain information concerning the outstanding Lumos options held by Lumos' current directors and executive officers, as of December 31, 2019, after giving effect to the applicable exchange ratios:

Options	Grant Date	Expiration Date	Exercise Price ($)	Numbers of Shares of Lumos Common Stock Underlying Option as of December 31, 2019	Numbers of Shares of Lumos Common Stock Underlying Option Vested as of December 31, 2019
Robert Heft	8/12/2014	8/12/2024	$ 0.15	147,977	147,977
Richard J. Hawkins	6/27/2019	6/27/2029	$ 0.21	176,658	117,771(1)
John C. McKew, Ph.D.	7/11/2016	7/11/2026	$ 0.54	735,362	735,362(2)
John C. McKew, Ph.D.	1/18/2018	1/18/2028	$ 0.28	86,270	68,295(3)
John C. McKew, Ph.D.	8/29/2018	8/29/2028	$ 0.28	58,886	58,886

(1) Reflects the acceleration of 50% of the then unvested shares of common stock underlying the stock option, effective as of the closing of the Merger pursuant to its change of control provision.

(2) Reflects the acceleration of 50% of the then unvested shares of common stock underlying the stock option, effective as of the closing of the Merger pursuant to its change of control provision.

(3) Reflects the acceleration of 50% of the then unvested shares of common stock underlying the stock option, effective as of the closing of the Merger pursuant to its change of control provision.

The foregoing discussion of the interests of the Lumos directors and officers in the Merger does not reflect the effect of the reverse stock split.

Stockholders' Rights

Both NewLink and Lumos are incorporated under the laws of the State of Delaware and, accordingly, the rights of the NewLink stockholders and Lumos stockholders are currently, and will continue to be, governed by the DGCL. If the Merger is completed, Lumos stockholders will become NewLink stockholders, and their rights will be governed by the DGCL, the Charter and the Bylaws of NewLink. The rights of NewLink stockholders contained in the Charter and Bylaws of NewLink will not materially change as a result of the Merger.

Regulatory Approvals

Neither NewLink nor Lumos is required to make any filings or to obtain approvals or clearances from any antitrust regulatory authorities in the United States or other countries to consummate the Merger. In the United States,

NewLink must comply with applicable federal and state securities laws and Nasdaq rules and regulations in connection with the issuance of shares of NewLink's common stock in the Merger, including the filing with the SEC of this proxy statement.

Federal Securities Law Consequences; Resale Restrictions

The issuance of NewLink's common stock in the Merger to Lumos stockholders will be effected by means of a private placement, which is exempt from registration under the Securities Act, in reliance on Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder and such shares will be "restricted securities." The shares issued in connection with the Merger will not be registered under the Securities Act upon issuance and will not be freely transferable. Holders of such shares may not sell their respective shares unless the shares are registered under the Securities Act or an exemption is available under the Securities Act. The Merger Agreement provides that NewLink will cooperate in a timely manner with the holders of such shares to remove any restrictive legends or similar transfer instructions from such shares upon the registration of such shares or in the event that such shares are otherwise transferable to an exemption from registration otherwise required thereunder.

Furthermore, the Merger Agreement provides that NewLink will, within 90 days after the closing of the Merger, file a registration statement on Form S-3 (or other appropriate form) to register all such shares for resale, and to use commercially reasonable efforts to cause such registration statement to be effective for three years so long as the shares of NewLink's common stock issued in the Merger remain outstanding without a transfer exemption under the Securities Act. See also "The Merger Agreement — Merger Consideration."

Material U.S. Federal Income Tax Consequences of the Reverse Stock Split and the Merger

The following discussion summarizes the material U.S. federal income tax considerations of the reverse stock split and Merger that would be expected to apply generally to U.S. Holders (as defined below) of NewLink's common stock. This summary is based upon current provisions of the Code, existing Treasury Regulations under the Code and current administrative rulings and court decisions, all of which are subject to change or different interpretation. Any change, which may or may not be retroactive, could alter the tax consequences to NewLink or the NewLink stockholders as described in this summary. No ruling from the U.S. Internal Revenue Service has been or will be requested in connection with the reverse stock split or, to the knowledge of NewLink, the Merger.

No attempt has been made to comment on all U.S. federal income tax consequences of the reverse stock split or the Merger that may be relevant to particular U.S. Holders, including holders: (i) who are subject to special tax rules such as dealers, brokers and traders in securities, mutual funds, regulated investment companies, real estate investment trusts, insurance companies, banks or other financial institutions or tax-exempt entities; (ii) who are subject to the alternative minimum tax provisions of the Code; (iii) who acquired their shares of NewLink's common stock in connection with stock options, stock purchase plans or other compensatory transactions; (iv) who hold their shares of NewLink's common stock as a hedge or as part of a hedging, straddle, "conversion transaction," "synthetic security," integrated investment or any risk reduction strategy; (v) who are partnerships, limited liability companies that are not treated as corporations for U.S. federal income tax purposes, S corporations, or other pass-through entities or investors in such pass-through entities; (vi) who do not hold their shares of NewLink's common stock as capital assets for U.S. federal income tax purposes (generally, property held for investment within the meaning of Section 1221 of the Code); (vii) who hold their shares NewLink's common stock through individual retirement or other tax-deferred accounts; (viii) whose shares of NewLink's common stock constitute qualified small business stock with the meaning of Section 1202 of the Code; or (ix) who have a functional currency for United States federal income tax purposes other than the U.S. dollar.

In addition, the following discussion does not address the tax consequences of the reverse stock split or the Merger under state, local and foreign tax laws, or the tax consequences of the Merger for the former holders of Lumos capital stock. The discussion assumes that for U.S. federal income tax purposes the reverse stock split will not be integrated or otherwise treated as part of a unified transaction with any other transaction, including the Merger. Furthermore, the following discussion does not address the tax consequences of transactions effectuated before, after or at the same time as the reverse stock split or the Merger, whether or not they are in connection with the reverse stock split or the Merger.

For purposes of this discussion, a U.S. Holder means a beneficial owner of NewLink's common stock who is: (i) an individual who is a citizen or resident of the United States; (ii) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in the United States or under the laws of the United States or any subdivision thereof; (iii) an estate the income of which is includible in gross income for

U.S. federal income tax purposes regardless of its source; or (iv) a trust (other than a grantor trust) if (A) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all substantial decisions of the trust or (B) it has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

HOLDERS OF NEWLINK STOCK ARE ADVISED AND EXPECTED TO CONSULT THEIR OWN TAX ADVISORS REGARDING THE U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE REVERSE STOCK SPLIT AND THE MERGER IN LIGHT OF THEIR PERSONAL CIRCUMSTANCES AND THE CONSEQUENCES OF THE REVERSE STOCK SPLIT AND THE MERGER UNDER STATE, LOCAL AND FOREIGN TAX LAWS.

Reverse Stock Split

- No gain or loss will be recognized by NewLink as a result of the reverse stock split.
- A NewLink stockholder who receives solely a reduced number of shares of common stock pursuant to the reverse stock split will generally recognize no gain or loss. A NewLink stockholder who receives cash in lieu of a fractional share interest will generally recognize gain or loss equal to the difference between (i) the portion of the tax basis of the pre-reverse stock split shares allocated to the fractional share interest and (ii) the cash received.
- A NewLink stockholder's basis in its post-reverse stock split shares, will be equal to the aggregate tax basis of such stockholder's pre-reverse stock split shares decreased by the amount of any basis allocated to any fractional share interest for which cash is received.
- The holding period of NewLink's common stock received in the reverse stock split will include the holding period of the pre-reverse stock split shares exchanged.
- Stockholders who acquired different blocks of NewLink's common stock at different times for different prices must calculate their basis, gains and losses, and holding periods separately for each identifiable block of such common stock exchanged, converted, canceled or received in the reverse stock split. U.S. Holders of NewLink's common stock acquired on different dates and at different prices should consult their tax advisors regarding the allocation of tax basis and the holding period of such shares.
- Any gain or loss recognized by a NewLink stockholder as a result of receiving cash in lieu of a fractional share interest will generally be a capital gain or loss and will be long term capital gain or loss if the stockholder's holding period for the relevant pre-reverse stock split shares exchanged is more than one year and will be short-term capital gain if such holding period is one year or less. Long-term capital gains of individuals are subject to tax at reduced rates.
- Any cash payments for fractional shares made to NewLink stockholders in connection with the reverse stock split may be subject to backup withholding on a holder's receipt of cash, unless such holder furnishes a correct taxpayer identification number and certifies that he or she is not subject to backup withholding or such stockholder is otherwise exempt from backup withholding, generally by providing a properly completed IRS Form W-9. Any amount withheld under the backup withholding rules will generally be allowed as a refund or credit against the holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

The Merger

NewLink and Lumos intend the Merger to qualify as a reorganization within the meaning of Section 368(a) of the Code. Each of NewLink and Lumos will use its reasonable best efforts to cause the Merger to qualify, and will not take any action or cause any action to be taken which action would reasonably be expected to prevent the Merger from qualifying, as a reorganization within the meaning of Section 368(a) of the Code.

NewLink stockholders will not sell, exchange or dispose of any shares of NewLink's common stock as a result of the Merger. Thus, there should be no material U.S. federal income tax consequences to NewLink stockholders as a result of the Merger. No tax opinion from NewLink's counsel nor, to the knowledge of NewLink, any Internal Revenue Service private letter ruling has been or will be obtained with respect to the tax consequences of the Merger.

ANTICIPATED ACCOUNTING TREATMENT

The Merger is expected to be treated by NewLink as a reverse merger and will be accounted for as an asset acquisition in accordance with GAAP as the assets acquired and liabilities assumed from NewLink do not meet the definition of a business as defined by ASC 805, *Business Combinations* as NewLink does not contain the processes in place to generate outputs. For accounting purposes, Lumos is considered to be acquiring the assets and liabilities of NewLink in this Merger. Management of NewLink and Lumos made a preliminary estimated allocation of the net assets acquired and liabilities assumed in connection with the transaction based on their estimated acquisition date fair values as described in Note 2 to the Unaudited Pro Forma Condensed Combined Financial Information. A final determination of these estimated fair values, which cannot be made prior to the completion of the Merger, will be based on the actual assets and liabilities of NewLink that exist as of the date of completion of the Merger.

THE MERGER AGREEMENT

The following is a summary of the material terms of the Merger Agreement. A copy of the Merger Agreement is attached as Annex A to this proxy statement and is incorporated by reference into this proxy statement. The Merger Agreement has been attached to this proxy statement to provide you with information regarding its terms. It is not intended to provide any other factual information about NewLink, Lumos or Merger Sub. The following description does not purport to be complete and is qualified in its entirety by reference to the Merger Agreement. You should refer to the full text of the Merger Agreement for details of the Merger and the terms and conditions of the Merger Agreement.

The Merger Agreement contains representations and warranties that NewLink and Merger Sub, on the one hand, and Lumos, on the other hand, have made to one another as of specific dates. These representations and warranties have been made for the benefit of the other parties to the Merger Agreement and may be intended not as statements of fact but rather as a way of allocating the risk to one of the parties if those statements prove to be incorrect. In addition, the assertions embodied in the representations and warranties are qualified by information in confidential disclosure schedules exchanged by the parties in connection with signing the Merger Agreement. While NewLink and Lumos do not believe that these disclosure schedules contain information required to be publicly disclosed under the applicable securities laws, other than information that has already been so disclosed, the disclosure schedules do contain information that modifies, qualifies and creates exceptions to the representations and warranties set forth in the Merger Agreement. Accordingly, you should not rely on the representations and warranties as current characterizations of factual information about NewLink or Lumos, because they were made as of specific dates, may be intended merely as a risk allocation mechanism between NewLink, Merger Sub and Lumos and are modified by the disclosure schedules.

General

Under the Merger Agreement, at the Effective Time, Merger Sub will merge with and into Lumos, with Lumos surviving as a wholly-owned subsidiary of NewLink.

Effective Time of the Merger

Unless the parties agree otherwise, the closing of the Merger will take place on the second business day following the satisfaction or waiver of all closing conditions, except for those conditions that, by their nature, have to be satisfied at the closing, but subject to the satisfaction or waiver of those conditions, or at such other time, date and place as NewLink and Lumos may mutually agree in writing. See "— Conditions to the Closing of the Merger" beginning on page 92 for a more detailed discussion of the conditions.

Merger Consideration

At the Effective Time, each share of Lumos' capital stock outstanding immediately prior to the Effective Time (excluding shares of Lumos' capital stock held as treasury stock or held by Lumos or Merger Sub and shares held by Lumos stockholders who have exercised and perfected appraisal rights) will automatically be converted into the right to receive a number of shares of NewLink's common stock equal to the exchange ratios applicable to such class and/or series of Lumos capital stock. Furthermore, the Merger Agreement provides that NewLink will, within 90 days after the closing of the Merger, file a registration statement on Form S-3 (or other appropriate form) to register all such shares of NewLink's common stock issued in the Merger, and to use commercially reasonable efforts to cause such registration statement to be effective for three years so long as such shares of NewLink's common stock remain outstanding without a transfer exemption under the Securities Act.

The Merger Agreement does not include a price-based termination right and there will be no adjustment to the total number of shares of NewLink's common stock that Lumos' stockholders and optionholders will be entitled to receive for changes in the market price of NewLink's common stock. Accordingly, the market value of the shares of NewLink's common stock issued pursuant to the Merger will depend on the market value of the shares of NewLink's common stock at the time the Merger closes, and could vary significantly from the market value on the date of this proxy statement.

No fractional shares of NewLink's common stock will be issuable to Lumos' stockholders pursuant to the Merger Agreement. Instead, each stockholder of Lumos who would otherwise be entitled to receive a fraction of a share of NewLink's common stock, after aggregating all fractional shares of NewLink's common stock issuable to such stockholder, will be entitled to receive, in lieu of such fraction of a share and upon surrender by such stockholder

of a letter of transmittal, in cash the dollar amount, rounded to the nearest whole cent, without interest, determined by multiplying such fraction by the volume weighted-average closing trading price of a share of NewLink's common stock on Nasdaq for the five consecutive trading days ending five trading days immediately prior to the date upon which the Merger becomes effective.

The Merger Agreement provides that, at the Effective Time, NewLink will deposit with an exchange agent acceptable to NewLink and Lumos certificates or evidence of book-entry shares representing NewLink's common stock issuable to Lumos' stockholders and a sufficient amount of cash to make payments in lieu of fractional shares.

The Merger Agreement provides that, promptly after the Effective Time, the exchange agent will mail to each record holder of Lumos' capital stock immediately prior to the Effective Time a letter of transmittal and instructions for surrendering and exchanging stock certificates representing shares of Lumos' capital stock held by such record holder in exchange for book-entry shares of NewLink's common stock. Upon surrender of a stock certificate representing shares of Lumos' capital stock for exchange to the exchange agent, together with a duly signed letter of transmittal and such other documents as the exchange agent or NewLink may reasonably require, the stock certificate surrendered will be cancelled and the holder of such stock certificate will be entitled to receive the following:

- a certificate or certificates or book-entry shares representing the number of whole shares of NewLink's common stock that such holder has the right to receive pursuant to the provisions of the Merger Agreement; and
- cash in lieu of any fractional share of NewLink's common stock.

At the Effective Time, all holders of certificates representing shares of Lumos' capital stock that were outstanding immediately prior to the Effective Time will cease to have any rights as Lumos stockholders. In addition, no transfer of Lumos' capital stock after the Effective Time will be registered on the stock transfer books of Lumos.

If any stock certificate representing shares of Lumos' capital stock has been lost, stolen or destroyed, NewLink may, in its discretion, and as a condition to the delivery of any book-entry shares of NewLink's common stock, require the owner of such lost, stolen or destroyed certificate to deliver an affidavit claiming such certificate has been lost, stolen or destroyed and indemnify NewLink against any claim suffered by NewLink related to the lost, stolen or destroyed certificate or any of NewLink's common stock issued in exchange for such certificate as NewLink may reasonably request.

From and after the Effective Time, until it is surrendered, each certificate that previously evidenced shares of Lumos' capital stock will be deemed to represent only the right to receive a certificate or book-entry shares of NewLink's common stock and cash in lieu of any fractional share of NewLink's common stock. NewLink will not pay dividends or other distributions on any shares of NewLink's common stock to be issued in exchange for any unsurrendered stock certificate representing shares of Lumos until the stock certificate is surrendered as provided in the Merger Agreement.

Exchange Ratios

The exchange ratio:

- *Common Stock Exchange Ratio*: with respect to Lumos common stock, is equal to (i) the quotient of (x) 1.18655352337665, divided by (y) the quotient of (i) 37,312,620, divided by the total number of shares of NewLink's common stock outstanding immediately prior to the Effective Time (excluding the issuance of shares of NewLink's common stock in respect of all options to purchase shares of NewLink's common stock and other outstanding options, warrants or rights to receive such shares, in each case, outstanding as of immediately prior to the Effective Time), multiplied by (ii) the quotient of (x) 8,933,437, divided by (y) the aggregate number of shares of Lumos common stock outstanding at the closing.
- *Series A Exchange Ratio*: with respect to Lumos Series A Preferred Stock, is equal to (i) the quotient of (x) 0.786153154291732, divided by (y) the quotient of (i) 37,312,620, divided by the total number of shares of NewLink's common stock outstanding immediately prior to the Effective Time (excluding the issuance of shares of NewLink's common stock in respect of all options to purchase shares of NewLink's common stock and other outstanding options, warrants or rights to receive such shares, in each case, outstanding as of immediately prior to the Effective Time), multiplied by (ii) the quotient of (x) 11,204,513, divided by (y) the aggregate number of shares of Lumos Series A Preferred Stock outstanding at the closing.

- *Series B Exchange Ratio*: with respect to Lumos Series B Preferred Stock, is equal to (i) the quotient of (x) 1.79647182727751, divided by (y) the quotient of (i) 37,312,620, divided by the total number of shares of NewLink's common stock outstanding immediately prior to the Effective Time (excluding the issuance of shares of NewLink's common stock in respect of all options to purchase shares of NewLink's common stock and other outstanding options, warrants or rights to receive such shares, in each case, outstanding as of immediately prior to the Effective Time), multiplied by (ii) the quotient of (x) 9,966,288, divided by (y) the aggregate number of shares of Lumos Series B Preferred Stock outstanding at the closing.

Under the exchange ratio formulas in the Merger Agreement, as of immediately after the Effective Time, NewLink stockholders will own approximately 50% of the outstanding common stock of the combined company following the Effective Time and the Lumos stockholders as of immediately prior to the Effective Time will own approximately 50% of the outstanding common stock of the combined company following the Effective Time. The final exchange ratios will be determined pursuant to a formula described in more detail in Lumos' Charter and the Merger Agreement. In addition, based on the number of outstanding equity awards and shares of capital stock of each of NewLink and Lumos as of December 31, 2019, immediately following the Effective Time (i) holders of NewLink common stock and equity awards are expected to own approximately 51.2% of the fully-diluted common stock of the combined company and (ii) holders of Lumos capital stock and equity awards are expected to own approximately 48.8% of the fully-diluted common stock of the combined company. As of December 31, 2019, and based on the closing price of the NewLink common stock on Nasdaq on December 31, 2019, outstanding NewLink options to acquire 848,485 shares of NewLink common stock are out-of-the-money (out of a total of outstanding NewLink options to acquire 3,483,422 shares of NewLink common stock on such date).

Treatment of Lumos Stock Options

At the Effective Time, each option to purchase shares of Lumos' common stock outstanding and unexercised immediately prior to the Effective Time under the Lumos 2012 Equity Incentive Plan (as amended, the "Lumos 2012 EIP") and Lumos 2016 Stock Plan (the "Lumos 2016 Plan" and together with Lumos 2012 EIP, "Lumos Plans"), whether or not vested, will be assumed by NewLink and converted into an option to purchase shares of NewLink's common stock and each option to purchase shares of Lumos' common stock assumed by NewLink will continue to be governed in accordance with the terms of the Lumos Plans and the terms of the stock option agreements by which such option is evidenced, but with changes to such documents as NewLink and Lumos mutually agree are appropriate to reflect the assumption and conversion of the Lumos options by NewLink to purchase shares of NewLink's common stock. From and after the Effective Time, each Lumos option assumed by NewLink may be exercised solely for such number of shares of NewLink's common stock as is determined by multiplying the number of shares of Lumos' common stock subject to the option by the Common Stock Exchange Ratio and rounding that result down to the nearest whole number of shares of NewLink's common stock. The per share exercise price of the converted option will be determined by dividing the existing exercise price of the option by the Common Stock Exchange Ratio and rounding that result up to the nearest whole cent. Any restrictions on the exercise of any Lumos option assumed by NewLink will continue following the assumption and conversion and the term, exercisability, vesting schedules and other provisions of assumed Lumos options will generally remain unchanged; *provided*, that any Lumos options assumed by NewLink may be subject to adjustment to reflect changes in NewLink's capitalization after the Effective Time and that the NewLink Board will succeed to the authority of the Lumos Board with respect to each assumed Lumos option. Furthermore, the Merger Agreement provides that NewLink will, within 20 days after the closing of the Merger, file a registration statement on Form S-8 to register the shares of NewLink's common stock underlying assumed Lumos options unless such shares are otherwise registered under the Securities Act.

Conditions to the Closing of the Merger

Each party's obligation to complete the Merger is subject to the satisfaction or waiver by each of the parties, at or prior to the closing, of various conditions, which include the following:

- there must not have been issued, and remain in effect, any temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Merger or any of the other transactions contemplated by the Merger Agreement by any court of competent jurisdiction or other governmental entity of competent jurisdiction, and no law, statute, rule, regulation, ruling or decree shall be in effect which has the effect of making the consummation of the Merger or any of the other transactions contemplated by the Merger Agreement illegal;

- the holders of a (i) a majority of the outstanding shares of Lumos' common stock and preferred stock, voting together as one class, (ii) a majority of the shares of Lumos' preferred stock, voting together as a single class, (iii) at least thirty two point three percent (32.3%) of the outstanding shares of Lumos' Series B preferred stock, voting together as a single class, must have, among other things adopted and approved the Merger Agreement and the transactions contemplated thereby;
- the holders of a majority of the outstanding shares of NewLink's common stock must have approved the Charter Amendment to effect a reverse stock split and the holders of a majority of the votes cast at the Special Meeting must have approved the issuance of NewLink's common stock in the Merger and the change of control of NewLink resulting from the Merger pursuant to the rules of Nasdaq; and
- the existing shares of NewLink's common stock must have been continually listed on Nasdaq through the closing of the Merger, NewLink must have caused the shares of NewLink's common stock to be issued in the Merger to be approved for listing on Nasdaq (subject to official notice of issuance) as of the closing of the Merger and NewLink must not have received any comment letter from the SEC or from officials of Nasdaq relating to the delisting or maintenance of listing of NewLink's common stock on Nasdaq.

In addition, each party's obligation to complete the Merger is subject to the satisfaction or waiver by that party of the following additional conditions:

- the representations and warranties regarding certain matters related to due organization and subsidiaries, authority and the binding nature of the agreement, capitalization and financial advisors of the other party in the Merger Agreement must be true and correct in all material respects on the date of the Merger Agreement and on the closing date of the Merger with the same force and effect as if made on the date on which the Merger is to be completed or, if such representations and warranties address matters as of a particular date, then as of that particular date;
- the remaining representations and warranties of the other party in the Merger Agreement must be true and correct on the date of the Merger Agreement and on the closing date of the Merger with the same force and effect as if made on the date on which the Merger is to be completed or, if such representations and warranties address matters as of a particular date, then as of that particular date, except in each case, or in the aggregate, where the failure to be so true and correct would not reasonably be expected to have a Company Material Adverse Effect or Parent Material Adverse Effect (each as defined in the Merger Agreement), as applicable (without giving effect to any references therein to any Company Material Adverse Effect or Parent Material Adverse Effect, as applicable, or other materiality qualifications);
- a Material Adverse Effect shall not have occurred to the other party to the Merger Agreement;
- the other party to the Merger Agreement must have performed or complied with in all material respects all of such party's agreements and covenants required to be performed or complied with by it under the Merger Agreement at or prior to the Effective Time;
- the other party must have delivered certain certificates and other documents required under the Merger Agreement for the closing of the Merger; and
- the party must have received from the other party lock-up agreements executed by certain stockholders of such party and each person who shall be elected or appointed as an executive officer or director of such party immediately following the closing.

In addition, the obligation of NewLink and Merger Sub to complete the Merger is further subject to the satisfaction or waiver of the following conditions:

- certain agreements between Lumos and its stockholders must have been terminated;
- Lumos must have filed a charter amendment to Lumos' Charter with the Secretary of State of the State of Delaware prior to the closing and such amendment shall be in full force and effect as of the closing; and
- either the period during which any holders of any class or series of Lumos capital stock can exercise their statutory appraisal rights under Section 262 of the DGCL with respect to the Merger shall have expired, and the holders of Lumos capital stock representing not more than zero-point-five percent (0.5%) of the votes entitled to be cast by holders of Lumos capital stock entitled to exercise such statutory appraisal rights shall have exercised (and not subsequently withdrawn or waived) such statutory appraisal rights; or the holders

of Lumos capital stock representing at least ninety-nine-point-five percent (99.5%) of the votes entitled to be cast by holders of Lumos capital stock entitled to exercise such statutory appraisal rights shall have effectively waived their statutory appraisal rights under Section 262 of the DGCL in connection with the Merger by execution and delivery of a written consent or waiver.

In addition, the obligation of Lumos to complete the Merger is further subject to the satisfaction or waiver of the following conditions:

- Lumos must have received a copy of the tax representation letter dated as of the closing date of the Merger, to the effect that the Merger will be treated, for U.S. federal income tax purposes, as a reorganization within the meaning of Section 368(a) of the Code; and
- NewLink must have caused the NewLink Board to be constituted as required by the Merger Agreement.

Representations and Warranties

The Merger Agreement contains customary representations and warranties of NewLink and Lumos for a transaction of this type relating to, among other things:

- corporate organization and power, and similar corporate matters;
- subsidiaries;
- authority to enter into the Merger Agreement and the related agreements;
- votes required for completion of the Merger and approval of the proposals that will come before the NewLink Special Meeting and that will be the subject of Lumos' stockholder written consent;
- non-contravention;
- consents;
- capitalization;
- financial statements and with respect to NewLink, documents filed with the SEC and the accuracy of information contained in those documents;
- material changes or events;
- liabilities;
- title to assets;
- real property and leaseholds;
- intellectual property;
- the validity of material contracts to which the parties or their subsidiaries are a party and any violation, default or breach to such contracts;
- regulatory compliance, permits and restrictions;
- legal proceedings and orders;
- tax matters;
- employee and labor matters and benefit plans;
- environmental matters;
- insurance;
- any brokerage or finder's fee or other fee or commission in connection with the Merger;
- transactions with affiliates;
- anti-bribery laws;
- with respect to NewLink, Stifel's opinion; and
- with respect to NewLink, the valid issuance in the Merger of NewLink's common stock.

The representations and warranties are, in many respects, qualified by materiality and knowledge, and will not survive the Merger, but their accuracy forms the basis of certain conditions to the obligations of NewLink and Lumos to consummate the Merger.

Operation of Business Pending the Merger

Subject to certain exceptions, the parties have agreed, and NewLink has agreed to cause Merger Sub to agree, to certain customary covenants during the period commencing on September 30, 2019 and continuing until the earlier of the termination of the Merger Agreement and the Effective Time, which include (i) conducting its business and operations in the ordinary course of business and in compliance in all material respects with all applicable laws and requirements of all material contracts, (ii) keeping in full force and effect all material insurance policies and (iii) taking no action that would materially affect or delay the ability of the any of the parties to the Merger from obtaining any necessary approvals required by the Merger Agreement, performing its covenants or agreements under the Merger Agreement or otherwise materially delay or prohibit the transactions contemplated by the Merger Agreement. In addition, none of the parties will take certain actions without the prior written consent of the other party.

Offers to Employees

In connection with the Merger, the parties have made certain offers to employees. Each current employee of Lumos will be offered the opportunity to continue employment with NewLink, Lumos or any affiliate thereof after the Effective Time. During the period beginning as of the Effective Time and ending no earlier than the first anniversary of the Effective Time, NewLink will:

- provide each of the continuing employees of NewLink, Lumos or any affiliates thereof with at least the same level of base wages or base salary (but excluding incentive compensation and equity-based compensation opportunities) that were provided to such employee immediately prior to the Effective Time and employee benefits that are substantially similar in the aggregate to the employee benefits that were provided to such employee immediately prior to the closing;
- grant each of the continuing employees credit for any service to Lumos or its affiliates earned prior to the closing for purposes of eligibility, vesting and determination of the level of benefits, vacation or paid time off accrual and severance benefit determinations, under any benefit or compensation plan, program, agreement or arrangement in which such employee participates that may be established or maintained after the closing;
- waive all pre-existing condition exclusions and actively-at-work requirements and similar limitations, eligibility waiting periods and evidence of insurability requirements under any benefit or compensation plan, program, agreement or arrangement in which such employee participates that may be established or maintained after the closing, to the extent waived or satisfied by a continuing employee under any Lumos benefit plan as of the closing; and
- waive any deductible, co-insurance and covered out-of-pocket expenses paid on or before the closing by any continuing employee (or covered dependent thereof) to be taken into account for purposes of satisfying the corresponding deductible, coinsurance and maximum out-of-pocket provisions after the closing under any applicable benefit or compensation plan, program, agreement or arrangement in which such employee participates that may be established or maintained after the closing in the same plan year in which the closing occurs.

No Solicitations

Each of NewLink and Lumos agreed that during the period commencing on the date of the Merger Agreement and ending on the earlier of the Effective Time or the termination of the Merger Agreement, except as described below, NewLink and Lumos and each of their respective subsidiaries will not, nor will either party or any of its subsidiaries authorize any of their directors, officers, employees, agents, attorneys, accountants, investment bankers, advisors or representatives to, directly or indirectly:

- solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of, any “acquisition proposal” or “acquisition inquiry” or take any action that could reasonably be expected to lead to an acquisition proposal or acquisition inquiry;

- furnish any non-public information with respect to it to any person in connection with or in response to an acquisition proposal or acquisition inquiry;
- engage in discussions or negotiations with any person with respect to any acquisition proposal or acquisition inquiry;
- approve, endorse or recommend an acquisition proposal;
- execute or enter into any letter of intent or similar document or any contract contemplating or otherwise relating to any acquisition transaction (other than a confidentiality agreement pursuant to the specified terms permitted by the Merger Agreement); or
- publicly propose to do any of the above.

An "acquisition inquiry" means an inquiry, indication of interest or request for information (other than an inquiry, indication of interest or request for information made or submitted by Lumos, on the one hand, or NewLink, on the other hand, to the other party) that would reasonably be expected to lead to an acquisition proposal.

An "acquisition proposal" means any offer or proposal, whether written or oral (other than an offer or proposal made or submitted by or on behalf of Lumos or any of its affiliates, on the one hand, or by or on behalf of NewLink or any of its affiliates, on the other hand, to the other party) contemplating or otherwise relating to any "acquisition transaction."

An "acquisition transaction" means any transaction or series of related transactions involving:

- any merger, consolidation, amalgamation, share exchange, business combination, issuance or acquisition of securities, reorganization, recapitalization, tender offer, exchange offer or similar transaction: (i) in which NewLink, Lumos or Merger Sub is a constituent entity, (ii) in which any individual, entity, governmental entity, or "group," as defined under applicable securities laws, directly or indirectly acquires beneficial or record ownership of securities representing more than 20% of the outstanding securities of any class of voting securities of NewLink, Lumos or Merger Sub or any of their respective subsidiaries or (iii) in which NewLink, Lumos or Merger Sub or any of their respective subsidiaries issues securities representing more than 20% of the outstanding securities of any class of voting securities of such party or any of its subsidiaries; or
- any sale, lease, exchange, transfer, license, acquisition or disposition of any business or businesses or assets that constitute or account for 20% or more of the consolidated book value or the fair market value of the assets of NewLink, Lumos or Merger Sub and their respective subsidiaries, as applicable, taken as a whole.

Notwithstanding the foregoing, before obtaining the applicable approvals of the NewLink stockholders or Lumos stockholders required to consummate the Merger, as applicable, each party may furnish non-public information regarding such party and its subsidiaries to, and may enter into discussions or negotiations with, any third-party in response to a bona fide acquisition proposal made or received after the date of the Merger Agreement, which such party's board of directors determines in good faith, after consultation with such party's outside financial advisors or outside legal counsel, constitutes or is reasonably likely to result in a "superior offer," as defined below, if:

- neither such party nor any representative of such party has materially breached the solicitation provisions of the Merger Agreement;
- such party's board of directors concludes in good faith, based on the advice of outside legal counsel, that the failure to take such action is reasonably likely to be inconsistent with the fiduciary duties of such board of directors under applicable legal requirements;
- such party gives the other party at least two business days' prior written notice of the identity of the third-party and of that party's intention to furnish information to, or enter into discussions with, such third-party before furnishing any information or entering into discussions with such third-party;
- such party receives from the third-party an executed confidentiality agreement containing provisions at least as favorable to such party as those contained in the confidentiality agreement between NewLink and Lumos; and
- at least two business days prior to the furnishing of any non-public information to a third-party, such party furnishes the same non-public information to the other party to the extent not previously furnished.

A "superior offer" means an unsolicited, bona fide written acquisition proposal (with all references to 20% in the definition of acquisition transaction being treated as references to greater than 80% for these purposes) that (a) was not obtained or made as a direct or indirect result of a breach, or violation, of the Merger Agreement, and (b) is on terms and conditions that the board of directors of the party receiving the offer determines in good faith, based on such matters that it deems relevant (including the likelihood of consummation of the transaction), as well as any written offer by the other party to the Merger Agreement to amend the terms of the Merger Agreement, and following consultation with outside legal counsel and outside financial advisors, if any, are more favorable, from a financial point of view, to that party's stockholders than the terms of the Merger.

The Merger Agreement also provides that each party will promptly advise the other of the status and terms of, and keep the other party reasonably informed with respect to, any acquisition proposal or any inquiry, indication of interest or request for information that would reasonably be expected to lead to an acquisition proposal or any material change or proposed material change to that acquisition proposal or inquiry, indication of interest or request for information that would reasonably be expected to lead to an acquisition proposal.

Meetings of Stockholders

NewLink is obligated under the Merger Agreement to call, give notice of and hold the NewLink Special Meeting for the purposes of considering the approval of the issuance of shares of NewLink's common stock to Lumos' stockholders in the Merger and the resulting "change of control" of NewLink under Nasdaq rules and the Reverse Stock Split Proposal.

Lumos is obligated under the Merger Agreement to obtain written consents of its stockholders sufficient to adopt the Merger Agreement thereby approving the Merger and related transactions, which Lumos obtained in September 2019.

Termination of the Merger Agreement

The Merger Agreement may be terminated at any time before the completion of the Merger, whether before or after the required stockholder approvals to complete the Merger have been obtained, as follows:

- by mutual written consent of NewLink and Lumos;
- by either NewLink or Lumos if the Merger shall not have been consummated by March 30, 2020 (the "End Date"); provided, however, that this right to terminate the Merger Agreement will not be available to any party whose action or failure to act has been a principal cause of the failure of the Merger to occur on or before the End Date and such action or failure to act constitutes a breach of the Merger Agreement; and provided, further, that the End Date shall be extended by 60 days upon request of either party if a request for additional information has been made by any government authority, or in the event that the SEC has not concluded its review of the preliminary proxy statement by such date;
- by either NewLink or Lumos if a court of competent jurisdiction or governmental entity has issued a final and nonappealable order, decree or ruling or taken any other action that has the effect of permanently restraining, enjoining or otherwise prohibiting the Merger or any of the other transactions contemplated by the Merger Agreement; provided, however, that this right to terminate the Merger Agreement will not be available to any party whose action or failure to act has been a principal cause of the issuance of such order, decree or ruling or the taking of such other action or such action or failure to act constitutes a breach of the Merger Agreement;
- by NewLink if Lumos' stockholder consent evidencing the required Lumos stockholder vote has not been obtained immediately following the execution of the Merger Agreement; provided, however, that this right to terminate the Merger Agreement will not be available to NewLink once Lumos obtains such stockholder vote and such vote continues in full force and effect;
- by either NewLink or Lumos if the NewLink special meeting shall have been held and completed and NewLink stockholders shall have taken a final vote and shall not have approved the Merger Proposal (Proposal 1) and the Reverse Stock Split Proposal (Proposal 2);
- by NewLink or Lumos if the other party has breached any of its representations, warranties, covenants or agreements contained in the Merger Agreement or if any representation or warranty of the other party has become inaccurate, in either case such that the conditions to the closing of the Merger would not be

satisfied as of time of such breach or inaccuracy, but if such breach or inaccuracy is curable, then the Merger Agreement will not terminate pursuant to this provision as a result of a particular breach or inaccuracy until the expiration of a 30-day period after delivery of written notice of such breach;

- by Lumos, at any time prior to the approval by NewLink stockholders of the proposals to be considered at the NewLink Special Meeting, if any of the following circumstances shall occur (each of the following, a "NewLink Board Adverse Recommendation Change");
- the NewLink Board withholds, amends, withdraws, qualifies or modifies its recommendation that the NewLink stockholders vote to approve the Merger Proposal (Proposal 1) or the Reverse Stock Split Proposal (Proposal 2) (or publicly proposes to do the same) in a manner adverse to Lumos; and
- the NewLink Board fails to recommend, in a proxy statement, against any acquisition proposal or alternative transactions within ten business days after the commencement of such acquisition proposal or alternative acquisition transaction.

Termination Fees and Expenses

Fee payable by NewLink

NewLink must pay Lumos a termination fee of $2.0 million if:

- the Merger Agreement is terminated by either NewLink or Lumos if the NewLink Special Meeting shall have been held and completed, and NewLink stockholders shall have not approved the Merger Proposal (Proposal 1) and the Reverse Stock Split Proposal (Proposal 2);
- the Merger Agreement is terminated by NewLink after the End Date and NewLink stockholders have not approved the Merger Proposal (Proposal 1) and the Reverse Stock Split Proposal (Proposal 2); or
- a NewLink Board Adverse Recommendation Change has occurred.

Fee payable by Lumos

Lumos must pay NewLink a termination fee of $2.0 million if:

- the Merger Agreement is terminated by NewLink if Lumos' stockholder consent evidencing the required Lumos stockholder vote has not been obtained immediately following the execution of the Merger Agreement; or
- the Merger Agreement is terminated by Lumos after the End Date and Lumos has not obtained Lumos' stockholder consent evidencing the required Lumos stockholder vote at the time of such termination.

Amendments

The Merger Agreement may be amended by the parties at any time if such amendment is in writing, is approved by the boards of directors of each party to the Merger Agreement and is signed by each party to the Merger Agreement, except that after the Merger Agreement has been adopted and approved by the NewLink stockholders or Lumos stockholders, no amendment that by law requires further approval by the NewLink stockholders or Lumos stockholders, as the case may be, shall be made without the further approval by such stockholders.

Governing Law

The Merger Agreement is governed by, and construed in accordance with, the laws of the State of Delaware, regardless of the laws that might otherwise govern under applicable principles of conflicts of laws. In any action or proceeding between any of the parties arising out of or relating to the Merger Agreement, each of the parties has: irrevocably and unconditionally consented and submitted to the exclusive jurisdiction and venue of the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware or, to the extent that neither of the foregoing courts has jurisdiction, the Superior Court of the State of Delaware; agreed that all claims in respect of such action or proceeding shall be heard and determined exclusively in accordance with the agreed exclusive jurisdiction and venue; waived any objection to laying venue in any such action or proceeding in such courts; waived any objection that such courts are an inconvenient forum or do not have jurisdiction over any party; and irrevocably and unconditionally waived the right to trial by jury.

ANCILLARY AGREEMENTS RELATED TO THE MERGER

Lock-up Agreements

Concurrently with entering into the Merger Agreement, all executive officers and directors of NewLink and Lumos and certain of NewLink stockholders and Lumos stockholders and their affiliates entered into lock-up agreements, pursuant to which such parties have agreed not to, except in limited circumstances, offer, pledge, sell, contract to sell, transfer or dispose of, directly or indirectly, or engage in swap or similar transactions with respect to, any shares of NewLink's common stock or any security convertible into or exercisable or exchangeable for NewLink's common stock, including, as applicable, shares received in the Merger and issuable upon exercise of certain options, during the period commencing at the Effective Time and continuing until the date that is 180 days from the Effective Time.

As of December 31, 2019, the NewLink directors, officers and other stockholders that are party to the lock-up agreements (including affiliated entities) owned an aggregate of 8,054,481 shares of NewLink's common stock representing approximately 21.6% of the outstanding shares of NewLink's common stock as of that date.

Support Agreements

In order to induce Lumos to enter into the Merger Agreement, all executive officers and directors of NewLink and certain NewLink stockholders and their affiliates entered into support agreements with NewLink pursuant to which, among other things, each such stockholder has agreed, solely in his, her or its capacity as a stockholder of NewLink, to vote all of his, her or its shares of NewLink's common stock in favor of (i) the amendment of NewLink's Charter to effect the Reverse Stock Split Proposal, (ii) the issuance of shares of NewLink's common stock to Lumos' stockholders in connection with the Merger; (iii) the change of control of NewLink resulting from the Merger pursuant to the Nasdaq rules, and (iv) any proposal submitted to the NewLink stockholders in accordance with Section 14A of the Exchange Act and the applicable SEC rules issued thereunder, seeking advisory approval of NewLink stockholders for a non-binding, advisory vote to approve certain compensation that may become payable to NewLink's named executive officers in connection with the completion of the Merger. Additionally, each such stockholder has agreed, solely in his, her or its capacity as a stockholder of NewLink, to vote against any competing acquisition proposal. These NewLink stockholders have also granted Lumos an irrevocable proxy to vote their respective shares in accordance with the support agreements. Lumos has agreed not to exercise the proxy granted therein for any purpose other than the purposes described in the support agreement. The support agreements prohibit each stockholder, solely in his, her or its capacity as a stockholder of NewLink, from soliciting or facilitating any competing acquisition proposal or acquisition inquiry.

Under these support agreements, subject to certain exceptions, such stockholders also have agreed not to sell or transfer their shares of NewLink's common stock and securities held by them until the earlier of the termination of the Merger Agreement or the completion of the Merger. To the extent that any such sale or transfer is permitted pursuant to the exceptions included in the support agreements, each person to which any shares of NewLink's common stock or securities are so sold or transferred must agree in writing to be bound by the terms and provisions of the support agreement, subject to certain further exceptions.

As of December 31, 2019, the NewLink stockholders that are party to a support agreement (including affiliated entities) owned an aggregate of 8,054,481 shares of NewLink's common stock representing approximately 21.6% of the outstanding shares of NewLink's common stock as of that date.

PROPOSAL 1

APPROVAL OF THE MERGER PROPOSAL

At the Special Meeting, NewLink stockholders will be asked to approve the issuance of NewLink's common stock pursuant to the Merger Agreement and the resulting "change of control" of NewLink under Nasdaq rules. Immediately following the Effective Time, NewLink stockholders will own approximately 50% of the outstanding common stock of the combined company and Lumos stockholders will own approximately 50% of the outstanding common stock of the combined company. Without giving effect to the proposed reverse stock split of NewLink's common stock described elsewhere in this proxy statement, and based on the foregoing percentages as of December 31, 2019 if such date were the closing date of the Merger:

- the Common Stock Exchange Ratio for the Lumos' common stock would be approximately 1.1777223185 shares of NewLink's common stock for each share of Lumos common stock;
- the Series A Exchange Ratio for the Lumos' Series A Preferred Stock would be approximately 0.7864159103 shares of NewLink's common stock for each share of Lumos Series A Preferred Stock; and
- the Series B Exchange Ratio for the Lumos' Series B Preferred Stock would be approximately 1.7970722622 shares of NewLink's common stock for each share of Lumos Series B Preferred Stock.

See "The Merger Agreement — Exchange Ratios" beginning on page 91 of this proxy statement.

Based on an assumed Merger closing date of December 31, 2019, NewLink will be issuing approximately 37.3 million shares of its common stock and assuming Lumos options to acquire approximately 2.0 million shares of NewLink's common stock (on an as-converted to NewLink's common stock basis).

In addition, based on the number of outstanding equity awards and shares of capital stock of each of NewLink and Lumos as of December 31, 2019, immediately following the Effective Time (i) holders of NewLink common stock and equity awards are expected to own approximately 51.2% of the fully-diluted common stock of the combined company and (ii) holders of Lumos capital stock and equity awards are expected to own approximately 48.8% of the fully-diluted common stock of the combined company. As of December 31, 2019, and based on the closing price of the NewLink common stock on Nasdaq on December 31, 2019, outstanding NewLink options to acquire 848,485 shares of NewLink common stock are out-of-the-money (out of a total of outstanding NewLink options to acquire 3,483,422 shares of NewLink common stock on such date).

The terms of, reasons for and other aspects of the Merger Agreement and the issuance of NewLink's common stock pursuant to the Merger Agreement and the resulting "change of control" of NewLink under Nasdaq rules are described in detail in the other sections of this proxy statement.

The full text of the Merger Agreement is attached to this proxy statement as *Annex A*.

OUR BOARD OF DIRECTORS RECOMMENDS A VOTE IN FAVOR OF PROPOSAL 1.

PROPOSAL 2

APPROVAL OF THE REVERSE STOCK SPLIT PROPOSAL

General

At the Special Meeting, NewLink stockholders will be asked to approve the Charter Amendment to effect a reverse stock split of the issued and outstanding shares of NewLink's common stock. Upon the effectiveness of the Charter Amendment effecting the reverse stock split, the outstanding shares of NewLink's common stock will be combined into a lesser number of shares such that one share of NewLink's common stock will be issued for a specified number of shares, which shall be between five and nine, of outstanding NewLink's common stock, with the exact number within the range to be mutually agreed upon by NewLink and Lumos. The NewLink Board intends to effect a reverse stock split of the shares of NewLink's common stock at a ratio of between one-for-five to one-for-nine. The proposed Charter Amendment will effect the reverse stock split, as more fully described below, but will not change the number of authorized shares, or the par value, of NewLink's common stock.

If Proposal 2 is approved, the NewLink Board and Lumos will mutually determine the final reverse stock split ratio and the reverse stock split would become effective prior to the closing of the Merger. Only one reverse stock split may be effected in connection with this Proposal 2. NewLink's and Lumos' decision will be based on a number of factors, including market conditions, existing and expected trading prices for NewLink's common stock and the listing requirements of Nasdaq.

Even if the stockholders approve the reverse stock split, NewLink reserves the right not to effect the reverse stock split if the NewLink Board does not deem the reverse stock split to be in the best interests of NewLink and its stockholders. Furthermore, the NewLink Board may determine to effect the reverse stock split, if it is approved by the stockholders, even if the other proposals to be acted upon at the meeting are not approved, including the issuance of shares of NewLink's common stock in the Merger and the resulting "change of control" of NewLink under Nasdaq rules (Proposal 1), or if the Merger is not otherwise completed. If the Merger Agreement is terminated and the NewLink Board determines to nonetheless effect the reverse stock split, NewLink (rather than NewLink and Lumos jointly) will determine the final ratio of the reverse stock split, within the range approved by the NewLink stockholders.

Reasons for the Reverse Stock Split

Meeting the Initial Listing Criteria for Nasdaq

NewLink's common stock is currently listed on Nasdaq under the symbol "NLNK." NewLink has filed an initial listing application with Nasdaq to seek listing on Nasdaq for the combined company in connection with the Merger.

According to Nasdaq rules, an issuer must, in a case such as this, apply for initial inclusion following a transaction whereby the issuer combines with a non-Nasdaq entity, resulting in a change of control of the issuer and potentially allowing the non-Nasdaq entity to obtain a Nasdaq listing. Accordingly, the listing standards of Nasdaq will require NewLink to have, among other things, a $4.00 per share minimum bid price upon the closing of the Merger. Based on NewLink's closing price as of November 19, 2019, NewLink expects that a reverse stock split will be necessary in order to maintain the listing of NewLink's common stock on Nasdaq following the Merger.

Retain Listing on Nasdaq

To the extent the Merger is not completed, the principal reason for the reverse stock split would be to maintain NewLink's continued listing on Nasdaq, which requires NewLink to have, among other things, a $1.00 per share minimum bid price for 30 consecutive trading days, although there can be no assurance that the trading price of NewLink's common stock would be maintained at such level or that NewLink will be able to maintain the listing of its common stock on The Nasdaq Global Market under the ticker symbol "NLNK." If the minimum bid price for NewLink's common stock falls below $1.00, the NewLink Board may determine to effect the reverse stock split, if it is approved by the stockholders, even if the Merger is not otherwise completed, to maintain continued listing on Nasdaq.

The NewLink Board believes that maintaining its listing on Nasdaq may provide a broader market for NewLink's common stock and facilitate the use of NewLink's common stock in financing and other transactions.

Potential Increase to Investor Interest

On November 19, 2019, NewLink's common stock closed at $1.60 per share. An investment in NewLink's common stock may not appeal to brokerage firms that are reluctant to recommend lower priced securities to their clients. Investors may also be dissuaded from purchasing lower priced stocks because the brokerage commissions, as a percentage of the total transaction, tend to be higher for such stocks. Moreover, the analysts at many brokerage firms do not monitor the trading activity or otherwise provide coverage of lower priced stocks. Also, investment funds may be reluctant to invest in lower priced stocks. As a result, the NewLink Board may determine to effect the reverse stock split, if it is approved by the stockholders, even if the other proposals to be acted upon at the meeting are not approved, including the issuance of shares of NewLink's common stock in the Merger and the resulting "change of control" of NewLink under Nasdaq rules (Proposal 1), or if the Merger is not otherwise completed.

Maintain the Number of Shares Authorized

One of the effects of the reverse stock split will be to effectively increase the proportion of authorized shares which are unissued relative to those which are issued. This could result in the combined company being able to issue more shares without further stockholder approval. NewLink currently has no plans to issue shares, other than in connection with the Merger, and to satisfy obligations under NewLink's employee stock options and RSUs from time to time as these options and RSUs are exercised or vested, respectively. The reverse stock split will not affect the number of authorized shares of NewLink's common stock, which will continue to be 75,000,000.

Principal Effects of the Reverse Stock Split

If the stockholders approve the proposal to implement the reverse stock split, NewLink will amend its Charter to effect the reverse stock split. The text of the form of the proposed Charter Amendment is attached to this proxy statement as *Annex I*.

The reverse stock split will be effected simultaneously for all outstanding shares of NewLink's common stock. The reverse stock split will affect all of NewLink stockholders uniformly and will not affect any stockholder's percentage ownership interests in NewLink, except to the extent that the reverse stock split results in any of NewLink stockholders owning a fractional share. Common stock issued pursuant to the reverse stock split will remain fully paid and nonassessable. The reverse stock split will not affect NewLink's continuing to be subject to the periodic reporting requirements of the Exchange Act.

As of the effective time of the reverse stock split, NewLink will adjust and proportionately decrease the number of shares of NewLink's common stock reserved for issuance upon exercise of, and adjust and proportionately increase the exercise price (if applicable) of, all options and RSUs and other rights to acquire NewLink's common stock. In addition, as of the effective time of the reverse stock split, NewLink will adjust and proportionately decrease the total number of shares of NewLink's common stock that may be the subject of the future grants under NewLink's stock option plans.

As an example, the following table illustrates the effects of a five-for-one and a nine-for-one reverse stock split (without giving effect to the treatment of fractional shares) as of December 31, 2019:

	Prior to Reverse Stock Split	**After 5-for-1 Reverse Stock Split**	**After 9-for-1 Reverse Stock Split**
Common stock outstanding	37,325,091	7,465,018	4,147,232
Common stock issuable pursuant to outstanding equity awards	3,485,313	697,062	387,257

Procedure for Effecting Reverse Stock Split and Exchange of Stock Certificates

If NewLink stockholders approve the proposal to effect the reverse stock split, and if the NewLink Board still believes that a reverse stock split is in the best interests of NewLink and its stockholders, NewLink and Lumos will mutually determine the ratio of the reverse stock split to be implemented. NewLink will file the certificate of amendment with the Secretary of State of the State of Delaware prior to the Effective Time. If the Merger is not completed, NewLink may nonetheless effect a reverse stock split at a ratio to be determined solely by the NewLink Board within the range approved by the NewLink

stockholders. The NewLink Board may delay effecting the reverse stock split without resoliciting stockholder approval. Beginning on the effective date of the reverse stock split, each certificate representing pre-split shares will be deemed for all corporate purposes to evidence ownership of post-split shares.

As soon as practicable after the effective date of the reverse stock split, stockholders will be notified that the reverse stock split has been effected. NewLink expects that NewLink's transfer agent will act as exchange agent for purposes of implementing the exchange of stock certificates. Holders of pre-split shares will be asked to surrender to the exchange agent certificates representing pre-split shares in exchange for certificates representing post-split shares in accordance with the procedures to be set forth in a letter of transmittal to be sent by NewLink. No new certificates will be issued to a stockholder until such stockholder has surrendered such stockholder's outstanding certificate(s) together with the properly completed and executed letter of transmittal to the exchange agent. Any pre-split shares submitted for transfer, whether pursuant to a sale or other disposition, or otherwise, will automatically be exchanged for post-split shares. STOCKHOLDERS SHOULD NOT DESTROY ANY STOCK CERTIFICATE(S) AND SHOULD NOT SUBMIT ANY CERTIFICATE(S) UNLESS AND UNTIL REQUESTED TO DO SO.

Fractional Shares

No certificates or scrip representing fractional shares of NewLink's common stock will be issued in connection with the reverse stock split. Each holder of NewLink's common stock who would otherwise have been entitled to receive a fraction of a share of NewLink's common stock shall be entitled to receive, in lieu thereof, upon surrender of such holder's certificate(s) representing such fractional shares of NewLink's common stock, cash (without interest) in an amount equal to such fractional part of a share of NewLink's common stock multiplied by the closing price of NewLink's common stock as of the effective date of the reverse stock split (as adjusted to give effect to the reverse stock split, as applicable).

By authorizing the reverse stock split, stockholders will be approving the combination of any whole number of shares of common stock between and including five and nine into one share. The certificate of amendment filed with the Secretary of State of the State of Delaware effecting the reverse stock split will include only that number mutually agreed by NewLink and Lumos. In accordance with this resolution, the NewLink Board will not implement any amendment providing for a different split ratio.

NewLink stockholders should be aware that, under the escheat laws of the various jurisdictions where stockholders reside, where NewLink is domiciled, and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the effective date of the reverse stock split may be required to be paid to the designated agent for each such jurisdiction, unless correspondence has been received by NewLink or the exchange agent concerning ownership of such funds within the time permitted in such jurisdiction. Thereafter, stockholders otherwise entitled to receive such funds will have to seek to obtain them directly from the state to which they were paid.

Accounting Matters

The reverse stock split will not affect the common stock capital account on NewLink's balance sheet. However, because the par value of NewLink's common stock will remain unchanged on the effective date of the split, the components that make up the common stock capital account will change by offsetting amounts. Depending on the size of the reverse stock split the NewLink Board decides to implement, the stated capital component will be reduced and the additional paid-in capital component will be increased with the amount by which the stated capital is reduced. The per share net income or loss and net book value of NewLink will be increased because there will be fewer shares of NewLink's common stock outstanding. Prior periods' per share amounts will be restated to reflect the reverse stock split.

Potential Anti-Takeover Effect

Although the increased proportion of unissued authorized shares to issued shares could, under certain circumstances, have an anti-takeover effect, for example, by permitting issuances that would dilute the stock ownership of a person seeking to effect a change in the composition of the NewLink Board or contemplating a tender offer or other transaction for the combination of NewLink with another company, the reverse stock split proposal is not being proposed in response to any effort of which NewLink is aware to accumulate shares of NewLink's common stock or obtain control of NewLink, other than in connection with the Merger with Lumos, nor is it part of a plan by management to recommend a series of similar amendments to the NewLink Board and stockholders. Other than the proposals being submitted to NewLink stockholders for their consideration at the Special Meeting, the NewLink Board does not currently contemplate recommending the adoption of any other actions that could be construed to affect the ability of third parties to take over or change control of NewLink.

No Appraisal Rights

Under DGCL, NewLink stockholders are not entitled to appraisal rights with respect to the reverse stock split, and NewLink will not independently provide stockholders with any such right.

Material U.S. Federal Income Tax Consequences of the Reverse Stock Split

For information about the material U.S. federal income tax consequences of the reverse stock split, see "The Merger — Material U.S. Federal Income Tax Consequences of the Reverse Stock Split and the Merger" beginning on page 87 of this proxy statement.

OUR BOARD OF DIRECTORS RECOMMENDS A VOTE IN FAVOR OF PROPOSAL 2.

PROPOSAL 3

APPROVAL OF THE COMPENSATION PROPOSAL

As required by Section 14A of the Exchange Act and the applicable SEC rules issued thereunder, we are providing our stockholders the opportunity to vote to approve, on a non-binding, advisory basis, certain compensation that may be paid or become payable to our named executive officers that is based on or otherwise relates to the Merger, as described in "The Merger — Interests of NewLink's Directors and Executive Officers in the Merger — Golden Parachute Compensation" beginning on page 71. Accordingly, NewLink stockholders are being provided the opportunity to cast an advisory vote on such potential payments.

As an advisory vote, this proposal is not binding upon NewLink, Lumos, Merger Sub or the combined company and approval of this proposal is not a condition to the completion of the Merger. Because the merger-related executive compensation to be paid in connection with the Merger is based on the terms of the Merger Agreement as well as the contractual arrangements with NewLink's named executive officers, such compensation will be payable, regardless of the outcome of this advisory vote, if the Merger is consummated and the other conditions to payment of such compensation are satisfied. However, NewLink seeks the support of its stockholders and believes that stockholder support is appropriate because NewLink has a comprehensive executive compensation program designed to link the compensation of its executives with NewLink's performance and the interests of NewLink stockholders.

OUR BOARD OF DIRECTORS RECOMMENDS A VOTE IN FAVOR OF PROPOSAL 3.

PROPOSAL 4

APPROVAL OF THE ADJOURNMENT PROPOSAL

If there are insufficient votes at the time of the Special Meeting to approve the Merger Proposal (Proposal 1) and the Reverse Stock Split Proposal (Proposal 2), the Special Meeting may be adjourned to another time or place, if necessary or appropriate, to permit, among other things, further solicitation of proxies if necessary to obtain additional votes in favor of the Merger Proposal and the Reverse Stock Split Proposal, as applicable. We currently do not intend to propose adjournment at the Special Meeting if there are sufficient votes to approve the Merger Proposal and the Reverse Stock Split Proposal.

If, at the Special Meeting, the number of shares present or represented by proxy and voting in favor of the Merger Proposal and the Reverse Stock Split Proposal is insufficient to approve the corresponding proposal, we intend to move to adjourn or recess the Special Meeting in order to enable the NewLink Board to solicit additional proxies for approval of such proposal.

In Proposal 4, we are asking our stockholders to authorize the holder of any proxy solicited by the NewLink Board to vote in favor of granting discretionary authority to the proxy holders, and each of them individually, to adjourn the Special Meeting to another time and place for the purpose of soliciting additional proxies. If the stockholders approve Proposal 4, we could adjourn the Special Meeting and use the additional time to solicit additional proxies, including the solicitation of proxies from NewLink stockholders who have previously voted.

OUR BOARD OF DIRECTORS RECOMMENDS A VOTE IN FAVOR OF PROPOSAL 4.

NEWLINK'S BUSINESS

For a description of NewLink's business, please refer to "Item 1. Business" set forth in NewLink's Annual Report on Form 10-K for the year ended December 31, 2018, included as Annex B to this proxy statement, which section is incorporated by reference herein. For a description of legal proceedings NewLink is party to, please refer to "Item 3. Legal Proceedings" set forth in NewLink's Annual Report on Form 10-K for the year ended December 31, 2018, included as Annex B to this proxy statement, and "Item 1. Legal Proceedings" set forth in NewLink's Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2019, June 30, 2019 and September 30, 2019, included as Annex C, Annex D and Annex E to this proxy statement, which sections are incorporated by reference herein.

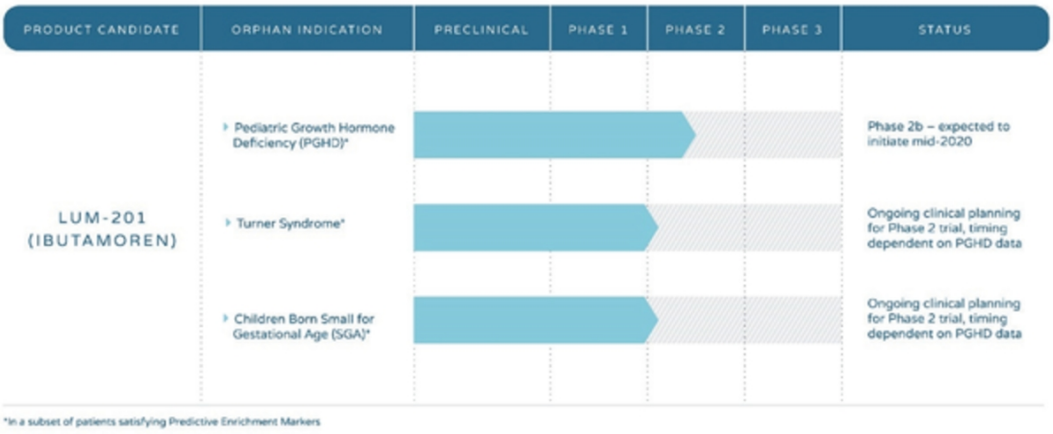
After the consummation of the Merger, the combined company expects to focus its efforts on the development of Lumos' sole product candidate, LUM-201, a potential oral therapy for PGHD and other rare endocrine disorders. NewLink management does not intend to pursue further internal development of its existing pipeline upon consummation of the Merger, but will continue to evaluate its pipeline pending results of the DIPG cohort of its Phase 1b clinical trial for indoximod and, depending on such results, may seek to identify potential partnerships and licensing opportunities.

LUMOS' BUSINESS

Overview

Lumos is a clinical-stage biopharmaceutical company focused on the identification, acquisition and in-license, development, and commercialization of novel products for the treatment of rare diseases. Lumos' mission is to develop new therapies for people with rare diseases, prioritizing its focus where the medical need is high, and the pathophysiology is clear. Lumos is committed to this mission and a strategy that is grounded upon time and cost-efficient drug development for Lumos to develop and deliver safe and effective therapies to patients. Driven by a sense of commitment to rare disease patients, their families and the rare disease community, the goal of Lumos is to be a leading rare disease drug company.

The current Lumos pipeline is focused on the development of an orally administered small molecule, the GH secretagogue LUM-201 for three rare endocrine disorders. A secretagogue is a substance that stimulates the secretion or release of another substance. LUM-201 stimulates the release of GH and is referred to as a GH secretagogue. The current targeted indications for LUM-201 are PGHD, Turner Syndrome and Children Born Small for Gestational Age ("SGA"), in each case in a certain subset of affected patients. Lumos is planning to initiate a clinical development program to study the effects of LUM-201 in PGHD in mid-2020 with a Phase 2b Trial. Depending on the outcome of data developed in the Phase 2b Trial and the timing of such data, Lumos plans to conduct Phase 2 clinical trials to study the effects of LUM-201 for Turner Syndrome and SGA in a certain subset of affected patients. The graphic below depicts these indications with their respective development status.



LUM-201 stimulates GH via the GH secretagogue receptor, also known as the ghrelin receptor ("GHSR1a"), thus providing a differentiated mechanism of action to treat some rare endocrine disorders (involving a deficiency of GH) by increasing the amplitude of endogenous, pulsatile GH secretion. LUM-201's stimulatory effect is regulated by insulin-like growth factor 1 ("IGF-1") feedback, hence protecting against hyperstimulation of GH. LUM-201 has been observed to stimulate endogenous GH in patients who have a functional but reduced hypothalamic pituitary GH axis. LUM-201 is a tablet formulation that will be administered orally once daily and provides a new therapeutic approach to the 34-year old standard of care (subcutaneous injectable rhGH) for treating rare endocrine disorders associated with GH deficiencies.

If approved, LUM-201 has the potential to become the first approved oral GH secretagogue to treat rare endocrine disorders associated with GH deficiencies, starting with PGHD, providing an alternative to the current standard regimen of daily injections.

LUM-201 for the Treatment of a Subset of PGHD Patients

Lumos is initially developing LUM-201 for a subset of patients with PGHD. PGHD is a rare endocrine disorder occurring in approximately one in 3,500 persons aged birth to 17 years. Causes of PGHD can be: congenital (children are born with the condition), acquired (brain tumor, head injuries or other causes), iatrogenic (induced by medical treatment) or idiopathic (of unknown cause). Children with untreated PGHD will have significant growth failure

(potential adult heights significantly less than five feet and may have abnormal body composition with decreased bone mineralization, decreased lean body mass and increased fat mass).

The main therapeutic goal in PGHD is to restore growth, enabling short children to achieve normal height and prevent complications that could involve metabolic abnormalities, cognitive deficiencies and reduced quality of life. Current treatment of PGHD is limited to daily subcutaneous injections of rhGH with a treatment cycle lasting up to an average of seven years. Poor compliance in daily rhGH injections for an average seven-year treatment regime results in an adverse impact on overall health efficacy.

LUM-201 is intended to provide an oral treatment to stimulate the release of endogenous GH in PGHD patients who have a functional but reduced hypothalamic pituitary GH axis and are expected to respond to LUM-201. Lumos believes this group represents 50% to 60% of PGHD patients. Lumos is planning to initiate a clinical development program to study the effects of LUM-201 in PGHD in mid-2020 with a Phase 2b dose finding, randomized study of approximately 80 pediatric subjects which will include an rhGH control arm.

Potential expansion of LUM-201 into additional endocrine indications

Lumos is also in the planning stages for developing LUM-201 for patients with Turner Syndrome. Turner Syndrome is a sex-linked developmental disorder that affects females only (one normal x chromosome, and the other x chromosome is either missing or structurally changed). It causes growth failure that begins before birth and continues into infancy and childhood, where it can be accentuated by the absence of puberty. If left untreated, girls with Turner Syndrome will usually achieve an average adult height that is significantly shorter than their peers.

Lumos is also in the planning stages for developing LUM-201 for the indication of SGA. SGA is a child born with birth weight and/or length under two standard deviations (“SDS”) for the gestational age and sex of the population. Approximately five percent of all newborn children are SGA and a spectrum of factors are found to be causative: maternal, placental, fetal, metabolic, and genetic. In the newborn period, SGA children are at greater risk of life-threatening conditions: hypoglycemia, hypercoagulability, necrotic enterocolitis, direct hyperbilirubinemia, and hypotension. Approximately 10% of SGA children do not achieve catch-up growth and remain short (≥-2 SDS) into adulthood.

Lumos History

Lumos was founded in 2011 by its current President and Chief Executive Officer, Richard Hawkins, who is the co-founder of Sensus, a company that developed Somavert® for the rare endocrine disease, acromegaly, that was later sold to Pharmacia Upjohn which was later sold to Pfizer. Mr. Hawkins is also the co-founder of Pharmaco, a CRO that merged with Pharmaceutical Product Development LLC (“PPD”), and the co-founder of Covance Biotechnology Services, a biotech services company that was later sold to Akzo Nobel.

Lumos has assembled an experienced team with extensive drug development and commercialization capabilities, particularly in the orphan drug area. Mr. Hawkins and the current team at Lumos have been previously involved, at other companies, in the development and/or commercialization of many therapies approved or in development for rare endocrine, neurological and metabolic genetic diseases, including Somavert®, Norditropin®, Increlex®, Abilify®, Carbaglu® and Orfadin®. Moreover, the management team also has strong experience in raising capital for drug development companies, including Lumos, Sensus, aTyr, and ACADIA.

Lumos’ focus, as a rare disease drug developer, started with the license from the University of Cincinnati of a preclinical compound cyclocreatine (“LUM-001”) a small molecule for the indication of Creatine Transporter Deficiency (“CTD”). CTD is an x-linked pediatric neurodevelopmental disorder, due to mutations of the SLC6A8 gene, that inhibits the transport of sufficient levels of creatine to the brain. Extensive preclinical development was performed by Lumos on LUM-001, as well as the initiation and completion of a Phase 1 trial in healthy volunteers. Lumos determined in April 2019 that the clinical path forward for LUM-001 was not viable due to safety signals in the non-clinical juvenile and chronic toxicology studies running concurrently with the Phase 1 clinical trial observed for the compound and the program was discontinued.

Lumos acquired LUM-201 from Ammonett in July 2018. See “— APA, Lumos Merck Agreement and Other Agreements— Ammonett and Lumos Merck Agreements” for additional information. LUM-201 received the ODD in the United States and the European Union for GHD in 2017, which is a necessary step in being granted market exclusivity for defined time periods in each of these markets upon approval. Lumos holds the United States patent 9763919 “Detecting and Treating Growth Hormone Deficiency,” which has been issued with an expiration in 2036

and could provide extended market protections beyond the United States ODD exclusivity period. Lumos is actively seeking similar patent protection in multiple jurisdictions worldwide. In addition, Lumos has filed a United States and Patent Cooperation Treaty ("PCT") application for LUM-201 in the treatment of Non-Alcoholic Fatty Liver Disease ("NAFLD"). See "— Intellectual Property" for more details.

Lumos Rare Disease Focus

Patient-focused drug development for rare diseases is the foundational focal point at Lumos. Rare disease patients and their caretakers inspire Lumos to learn as much as it can to persevere and continue to advance the development of potential therapies to treat rare diseases. For this reason, Lumos is committed to developing these therapies with the utmost urgency and care for these patients.

Lumos strives to build a rare disease company that is better and smarter about advancing product candidates through approval by engaging, early and often, the patient's perspective during the continuum of the drug development process. Lumos is dedicated to promoting a strong patient-centric philosophy amongst its partners and stakeholders. Lumos is grateful and honored to initiate and work on collaborative patient-focused projects such as increasing disease awareness, enabling better diagnostic modalities and access, and providing education and services to support patient and healthcare communities.

Lumos' Strategy

Lumos' strategy is to identify, acquire, develop, and commercialize novel products for the treatment of rare diseases on a global level, prioritizing direct commercialization in selected markets, beginning with the United States and seeking partnerships/licensing in other markets. The critical components of Lumos' business strategy include the following:

- focus on rare diseases with limited or no treatment options;
- focus on diseases and therapies with clear pathophysiology and mechanisms of action;
- leverage Lumos' experience and relationships to in-license promising product candidates from academic institutions, rare disease patient foundations, and/or derived from partnerships with other pharmaceutical companies;
- focus on creative, adaptive and rapid clinical and regulatory execution; and
- where possible, seek to retain global or broad commercialization rights to product candidates to maximize long-term value.

Driven by a sense of commitment to rare disease patients, their families and the rare disease community, the goal of Lumos is to be a leading rare disease drug company.

Patients with rare disorders are typically treated by a small number of specialists. As a result, Lumos expects its commercial structure to be modest in size with an emphasis on supporting programs to expedite patient finding capabilities and assistance to patients and healthcare providers to support market access relating to treatment and reimbursement support.

Potential Market Opportunity

In the United States, approximately one in 3,500 children are born with PGHD. Children with PGHD are characterized by short stature, metabolic abnormalities, cognitive deficiencies and poor quality of life. The current standard of care for PGHD is daily subcutaneous injections of rhGH, which dates back to 1985, and with donor-sourced GH since the 1950s. The worldwide sales of rhGH for PGHD were estimated to reach $1.12 billion in 2016 in the major markets, with such sales consisting of 65.2% in the United States, 20.6% in Japan, and 14.2% in the aggregate for the European markets of France, Germany, Italy, Spain and the United Kingdom.

Growth hormone-deficient children who are fully in adherence with their daily treatment regimen may achieve a height in adulthood that is comparable to that of their family members and national norms. Despite the demonstrated benefits of rhGH therapy, compliance continues to be a challenge, as patients treated with daily rhGH typically receive thousands of injections over the course of many years. For caregivers of young children and teenagers who likely have had to endure daily injections of rhGH for many years, the problem of needle fatigue – missing injections because of the pain, bruising or other effects of daily treatment – remains an important reason for noncompliance with daily treatment.

There are various approaches by the pharmaceutical industry to develop rhGH products to reduce the patient burden of daily injections and increase patient compliance with the dosing regimen, including longer-acting growth hormone treatments that would require less frequent injections. Lumos believes that an oral treatment may help a subset of PGHD patients to achieve better treatment results through better treatment compliance than is typical for the current standard of care.

If approved, LUM-201 will not be an appropriate treatment for all PGHD patients. Only patients with a demonstrated partially functioning hypothalamic-pituitary growth hormone HP-GH axis will be eligible for inclusion in future trials to determine the safety and efficacy of LUM-201. Lumos believes, based on data generated to date, that the proportion who fit such criteria is approximately 50% to 60% of all PGHD subjects. See "— Lumos' Product Candidate — LUM-201 addressable PGHD population" and "— Post-hoc analysis and using a predictive enrichment marker strategy to select appropriate patients" for additional information regarding LUM-201's mechanism of action and other data related to the addressable PGHD population for LUM-201.

In addition to PGHD, there are multiple other indications for which treatment with rhGH has been approved by the FDA. Lumos intends to investigate the safety and efficacy of LUM-201 in some of these other indications, subject to corporate prioritization and funding resources. Depending on the outcomes of its Phase 2b Trial, Lumos is planning for Phase 2 trials to investigate LUM-201's safety and efficacy for a subset of patients with Turner Syndrome and SGA.

Lumos' Product Candidate

LUM-201 for the treatment of a subset of PGHD patients

Background

GHD in children and adults is the consequence of low or absent secretion of GH from the pituitary gland. The numerous causes include neoplasia, trauma, inflammation, surgery and/or irradiation of the central nervous system and genetic causes.

Children with untreated GHD will have significant growth failure with attainment of adult heights significantly less than five feet in many cases. In addition, they may have abnormal body composition with decreased bone mineralization, decreased lean body mass and increased fat mass. Characteristics of GHD children include height below the 2.3 percentile of the normal range for age and gender, attenuated height velocity, and delayed bone maturation.

GH is an anabolic hormone synthesized, stored in, and secreted from somatotrophs of the anterior pituitary gland in response to chemical modulators from the hypothalamus and stomach. Upon release, GH acts on growth hormone receptors ("GHR") in multiple tissues and alone, or in concert with its downstream effectors, regulates diverse physiological processes. GH has been shown to directly stimulate protein synthesis, cellular proliferation and differentiation, including proliferation of bone chondrocytes that lead to linear growth. GH also impacts carbohydrate and lipid metabolism, mediating a net inhibition of glucose uptake and glycolysis, an increase in free fatty acids, and a decrease in urinary nitrogen excretion.

Secretion of GH is under strict and complex hormonal homeostatic control with growth hormone releasing hormone ("GHRH" or "GRF") and ghrelin as the most significant stimulators of its production and somatostatin ("SST") and IGF-1 exerting inhibitory action. At the level of the hypothalamus, GHRH and SST are released into the portal system to exert positive and negative effects, respectively. The secretion of GHRH and SST are modulated by neurotransmitters whose concentrations vary in response to a number of metabolic and chemical factors. Once GH is released, it stimulates release of IGF-1 into the circulation, primarily from the liver, and this effector in turn exerts negative feedback at the level of both the pituitary and the hypothalamus to limit GH release. GH also limits itself by stimulating secretion of SST from the hypothalamus. IGF-1 is critical to the actions of GH in that it acts in synergy with GH to promote linear growth in children and in the control of metabolism and body-mass composition in adults. IGF-1 is regulated through its own complex feedback mechanisms, involving GH and IGF-1 binding protein complexes. Finally, ghrelin produced in the stomach stimulates GH release. The ghrelin receptor, also known as the growth hormone secretagogue receptor GHSR1a, is expressed in the hypothalamus and pituitary, amongst other tissues. Ghrelin, LUM-201 and other GH secretagogues act on GHSR1a specifically in the anterior pituitary and hypothalamus to stimulate the ultradian release of GH.

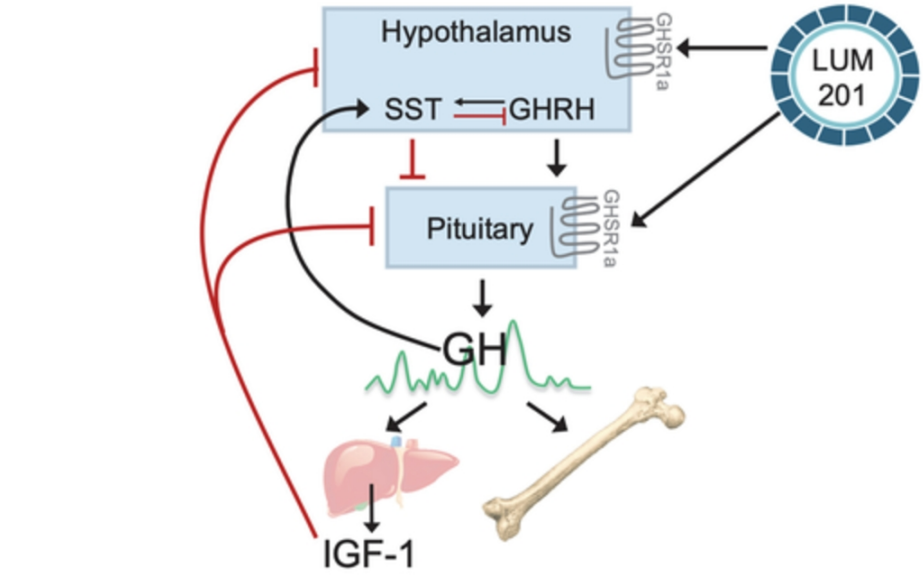
Current approved therapeutics and potential treatments

Current treatment of GHD children is limited to daily subcutaneous injections of rhGH. Daily administration of rhGH to prepubertal children with GHD does not mimic the daily pulsatile pattern of GH secretion, but nevertheless results in mean first year height velocities of 8.5 to 12 cm/yr, an improvement of 4 to 6 cm/yr over a patients previous six months of growth. Several patient pre-treatment characteristics have been found to correlate with higher first year velocities. First year height velocities are increased in younger patients, in those with greater initial height deficits and in those with more severe GHD (low stimulated GH response and/or low IGF-1 standard deviation scores). Treatment is required for an average of approximately seven years, but in the cases of congenital GHD may persist throughout life. Augmenting circulating GH levels with exogenous daily or weekly injections of GH forms (several of such weekly, or long-acting rhGH forms are currently in clinical development), has been proven to be an effective strategy for treating GHD in children.

Preclinical data supporting LUM-201's use in PGHD

Merck originally developed LUM-201 as a GH secretagogue that selectively acts on GHSR1a specifically in the anterior pituitary and hypothalamus to stimulate the ultradian release of GH. LUM-201 has demonstrated stimulatory GH responses following oral administration in mice, rats, dogs, pigs, and humans. The mechanism of action of LUM-201 is illustrated in Figure 1 below.

Figure 1: Mechanism of action of LUM-201

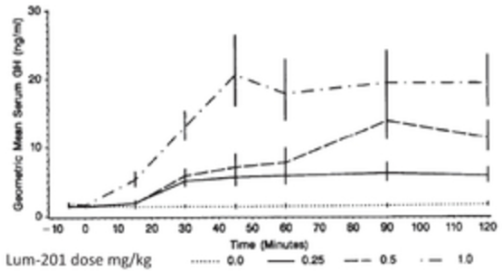


SST = somatostatin
IGF-1 = insulin-like growth factor-1
GHRH = growth hormone-releasing hormone
GHSR1a = GH secretagogue receptor 1a

GHSR1a activation via LUM-201 binding induces GH release, as demonstrated *in vitro* in rat pituicytes (LUM-201 EC_{50} 1.3 nM). In addition, the treatment of pituicytes with LUM-201 augments the effect of GHRH on GH secretion, as the two compounds synergistically stimulated GH release from rat pituitary cells, demonstrating distinct mechanisms of action.

Non-clinical evidence of the ability of LUM-201 to stimulate GH release is provided with the following example. In a crossover, randomized trial in eight fasting dogs, single doses of placebo or LUM-201 (0.25, 0.50, and 1 mg/kg) were administered orally with a seven-day interval between doses. Treatment with LUM-201 resulted in statistically significant, dose-dependent increases in both mean peak GH (C_{max}) and mean AUC, as shown in Figure 2 below. Mean GH C_{max} occurred 90 minutes (0.25 and 0.5 mg/kg) and 45 minutes (1.0 mg/kg) post-dose, with the GH levels remaining high at two hours post dose.

Figure 2: Geometric mean (±SEM) serum GH levels after single oral administration of LUM-201 in dogs



A comprehensive suite of pharmacology, pharmacokinetics and toxicology studies was conducted *in vitro* and *in vivo* in multiple, relevant non-clinical species. Potential drug-drug interactions were also evaluated *in vitro* in studies aligned with current regulatory guidance. Non-clinical testing focused mainly on daily oral administration of LUM-201, consistent with the intended clinical dose frequency and route. The toxicology studies completed by Merck with LUM-201 include acute, chronic, juvenile, developmental and reproductive, and carcinogenicity studies along with safety pharmacology studies. The results of these studies support the proposed clinical development plan.

Prior clinical experience with LUM-201 in adults

Merck's prior clinical experience with LUM-201 in adults consists of various single and multiple oral-dose trials in healthy young adult, diseased adults, GH-deficient adults, and elderly volunteers and patients conducted by Merck over a 13-year window that ended in 2006. Over 1,000 adult (including elderly) patients received at least one dose of LUM-201 at doses ranging from one to 200 mg. In these trials, LUM-201 was administered in tablet form. Approximately 500 subjects have received LUM-201 25 mg daily for at least six months. Over 200 subjects have been treated for as long as 12 months.

In a healthy elderly population given 25 mg per day of LUM-201, a sustained increase in circulating growth hormone levels and IGF-1 was observed. Both GH and IGF-1 geometric mean data show an increase from baseline at both six and 12 months of treatment as depicted in Figure 3 shown below. Additionally, a representative 24 hour GH release profile showed the LUM-201 induced increases in GH pulses compared to that patient's own baseline as depicted in Figure 4 shown below. Since GH release attenuates with age, healthy elderly people are growth hormone deficient compared to their younger healthy counterparts and can serve as a model for how growth hormone deficient children may respond to LUM-201.

Figure 3: Growth hormone and IGF-1 levels at baseline and at six and 12 months in a healthy elderly population treated with 25 mg per day of LUM-201

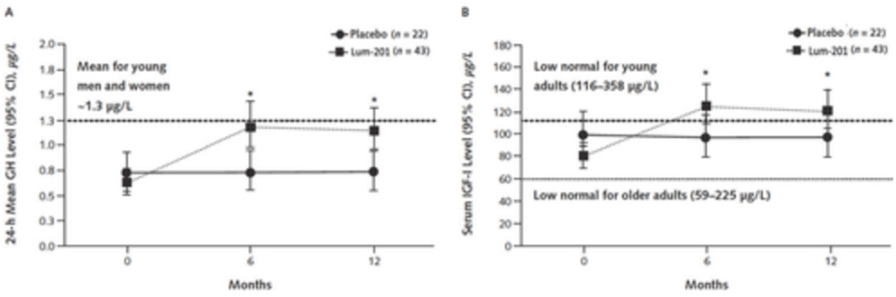
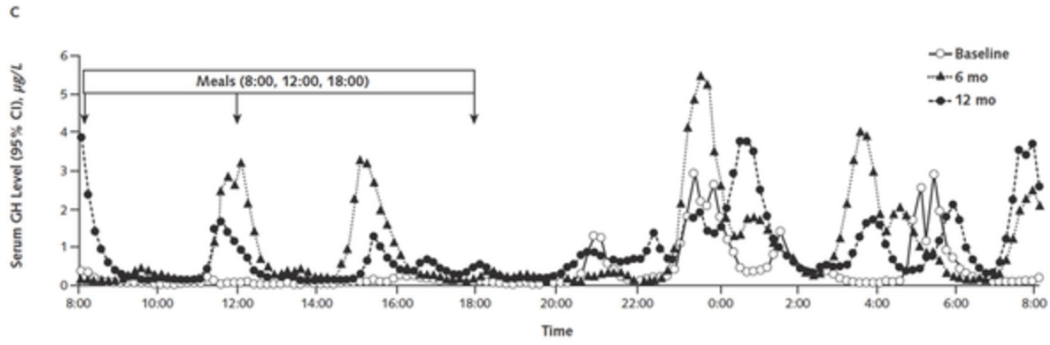


Figure 4: Representative 24 hour GH profile at baseline and at six and 12 months in a healthy elderly population treated with 25 mg per day of LUM-201



Prior clinical experience with LUM-201 in PGHD

Merck's prior clinical experience with LUM-201 in children occurred from 1996 to 1998 and consisted of three oral-dose trials in GHD children. A total of 204 previously diagnosed GHD children were enrolled into clinical trials and 157 children (67 of which were treatment naïve and 90 of which were previously rhGH treated subjects) received LUM-201 0.1 to 0.8 mg/kg administered daily as a liquid formulation for at least one week; 75 children were on therapy for at least six months. At the doses tested previously in the Merck Trials, LUM-201 was generally well-tolerated in children with the most common reported adverse events encompassing digestive systems events, including appetite increase. Mild elevations in liver enzymes without accompanying changes in bilirubin were also reported.

The first trial was a double-blind, placebo-controlled, sequential, rising-dose trial of the safety, tolerability, biologic response, and plasma drug concentration profile of single and multiple (up to eight days) oral doses of LUM-201 administered in PGHD subjects. The second trial was a double-blind, placebo-controlled, dose-range finding trial in naïve-to-treatment PGHD subjects to explore safety and efficacy in a six-month treatment paradigm with a safety extension. The final PGHD trial was a randomized dose-range finding, parallel group trial in PGHD subjects previously treated with rhGH that evaluated safety and efficacy in a 12-month treatment paradigm compared to a rhGH treated cohort. The first trial was completed successfully and showed that, for a subset of PGHD patients, there were increases of both serum GH and IGF-1 after LUM-201 administration. Both efficacy trials were terminated prior to completion based on a preliminary efficacy analysis of the PGHD subjects previously treated with rhGH. There was a change in formulation midway through the second, naïve-to-treatment trial (months six to 12) and during the entire course of the third, previously rhGH-treated trial. The change in formulation lowered the bioavailability by 30% to 40% and thus the exposure of LUM-201 and may have been a confounding factor when analyzing efficacy data.

Post-hoc analysis and using a predictive enrichment marker strategy to select appropriate patients

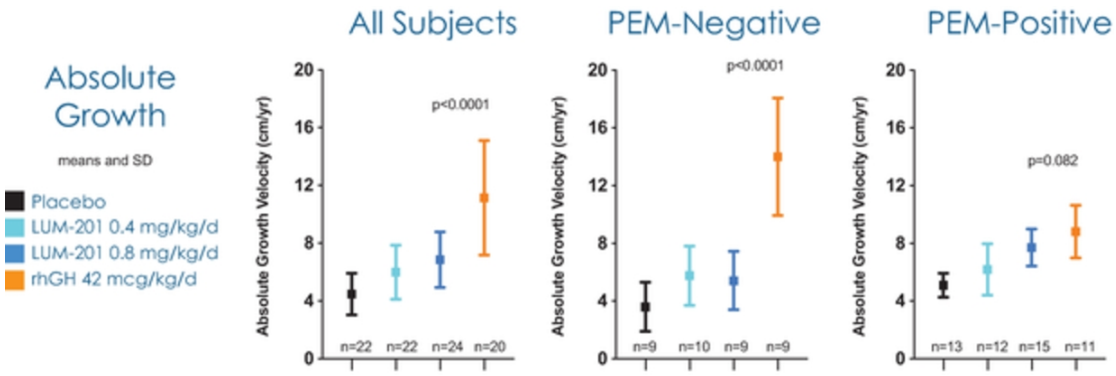
The use of predictive enrichment markers was examined in a post hoc analysis of the first six months of data from the naïve-to-treatment trial described above. An analysis of height velocity responses from months one to six of treatment with LUM-201 compared to rhGH treatment identified two distinct populations:

1. Subjects who are unable to secrete growth hormone and have a low potential for growth with LUM-201 versus rhGH treatment, and are defined by baseline serum IGF-1 ≤ 30 ng/ml and/or peak serum GH level of < 5 ng/ml in response to a single oral dose of 0.8 mg/kg LUM-201; **these children are defined as Predictive Enrichment Marker – Negative ("PEM-Negative")**; and

2. Subjects who can secrete some, but insufficient, GH will have an equivalent potential for growth with LUM-201 versus rhGH treatment, and are defined by baseline serum IGF-1 > 30 ng/ml and peak serum GH level ≥ 5 ng/ml in response to a single oral dose of 0.8 mg/kg LUM-201; **these children are defined as Predictive Enrichment Marker – Positive ("PEM-Positive")**.

Children treated with LUM-201 grew less well than those treated with rhGH when all children were considered together (Figure 5 left graph, all subjects). Notably, when only the PEM-Positive children are considered (Figure 5 right graph), the growth in response to 0.8 mg/kg LUM-201 was enhanced and growth due to rhGH treatment was reduced, when compared to all children.

Figure 5: Mean height velocity after treatment with placebo, rhGH or LUM-201 for six months in all subjects and in subjects identified as having lower growth potential (PEM-Negative) or having similar growth potential (PEM-Positive) in response to LUM-201 compared to rhGH



This dichotomy of patient response reflects the biology that LUM-201 can reactivate a reduced, but intact, hypothalamic pituitary GH axis and potentially restore growth in PEM-Positive patients. LUM-201 may have similar growth potential to rhGH in this set of patients. To clarify, in the PEM-Negative children (Figure 5 middle panel) with an axis that is not able to respond to LUM-201, growth in response to treatment with LUM-201 at either administered dose is statistically less than rhGH (t-test $p<0.0001$) and therefore rhGH is the preferred treatment. This is also reflected in the left panel of Figure 5, where the inclusion of the PEM-Negative patients who cannot respond to LUM-201 in the overall analysis of all subjects creates a negative confounding effect such that patients treated with rhGH had a growth velocity of 11.14 cm/yr, statistically greater than the growth velocity in the entire cohort of patients treated with 0.8 mg/kg LUM-201, of 6.85 cm/yr (t-test $p<0.0001$). However, in the PEM-Positive children whom Lumos believes have the potential to respond to LUM-201, the growth velocity was not statistically different between rhGH (8.81 cm/yr) and 0.8 mg/kg of LUM-201 (7.71 cm/yr) using a t-test ($p = 0.082$, Figure 5 right graph). This p-value is greater than the scientific standard of 0.05, commonly used in scientific evaluation, indicating that since the two treatments are not statistically different, they are potentially similar with regard to growth velocities. These data are not sufficient to demonstrate non-inferiority (the registration study endpoint accepted by the FDA for the approval of other treatments for PGHD) and therefore not sufficient to seek approval of LUM-201 at this time. Additionally, given the small number of patients, Lumos cannot exclude the possibility that the results are due to chance alone and may not be reproducible in a larger study. However, Lumos believes this post hoc analysis utilizing t-tests is adequate to generate the hypothesis that Lumos can allocate PGHD patients into PEM-Positive and PEM-Negative populations prospectively in planned clinical trials of LUM-201 in PGHD. Lumos' Phase 2 trial will explore this hypothesis prospectively and seek to determine a dose of LUM-201 that, when administered to PEM-Positive patients, can produce growth that is similar to PEM-Positive patients who are administered rhGH. If an appropriate dose is demonstrated by this Phase 2 trial, any planned Phase 3 trial will be designed to show non-inferiority to rhGH, and will need to satisfy the predefined statistical parameters of non-inferiority as agreed with the FDA at that time. The statistical parameters used to show non-inferiority in the Phase 3 trial will be distinct from the t-test used to analyze the previous data. The statistical analysis required to demonstrate efficacy of LUM-201, like any investigational drug candidate, is a matter of scientific, statistical, and regulatory review by the FDA and any approval of a drug candidate is a matter of comprehensive review of all available data by the FDA. There is no single p-value threshold or statistical methodology such as confidence interval that guarantees approval by the FDA. Lumos believes that its planned Phase 2b Trial using the previously described PEMs to select patients will provide the data needed to select an appropriate LUM-201 dose to use in a Phase 3 non-inferiority study or to show that the hypothesis is incorrect and there is no development path for LUM-201 in PGHD.

In order to better plan for appropriate doses for future clinical trials, Lumos analyzed previous clinical pharmacokinetic ("PK") / pharmacodynamic ("PD," and together with PK, "PK/PD") data in adults and children. Figure 6 is a graph of the PD effect (circulating growth hormone levels) found after increasing doses of LUM-201 are given to normal healthy volunteers. What can be observed is that increasing doses of LUM-201 stimulate the release of increasing amounts of circulating GH up until a 100 mg fixed dose of LUM-201. There is no increase in circulating GH when the dose is further increased to 200 mg. This indicates a plateau in GH release that may be initiated by the naturally occurring feedback mechanism discussed above. The effect of GHRH in this population is also shown (GRF in graph). Lumos sought to relate this PD effect in normal healthy adults to a PD response in growth hormone deficient children by plotting the GH Cmax of each curve in Figure 6 with the mean Cmax of PEM-Positive subjects enrolled in the treatment naïve (Study 020) trial after a single 0.8 mg/kg dose of LUM-201. The mean pediatric PD response (blue circle) falls on the adult PD dose response curve taking into account differences in exposure between adults and children and indicates that higher doses of LUM-201 in children with GHD should be able to produce more GH which has the potential to increase height velocity in children with a functional but underperforming axis.

Figure 6: Mean GH responses following single oral doses of LUM-201 and a single IV dose of GH releasing hormone (GRF) 1 ug/kg in healthy young male volunteers

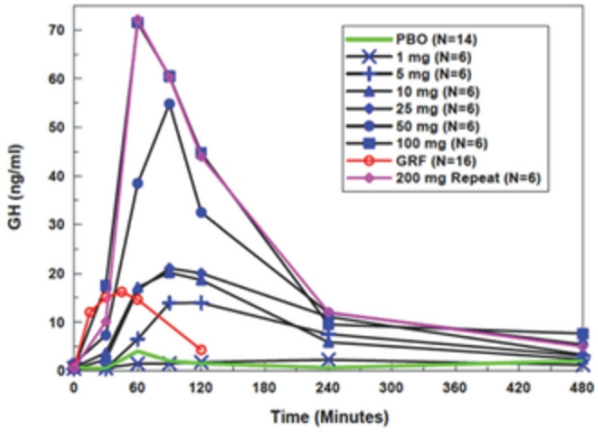
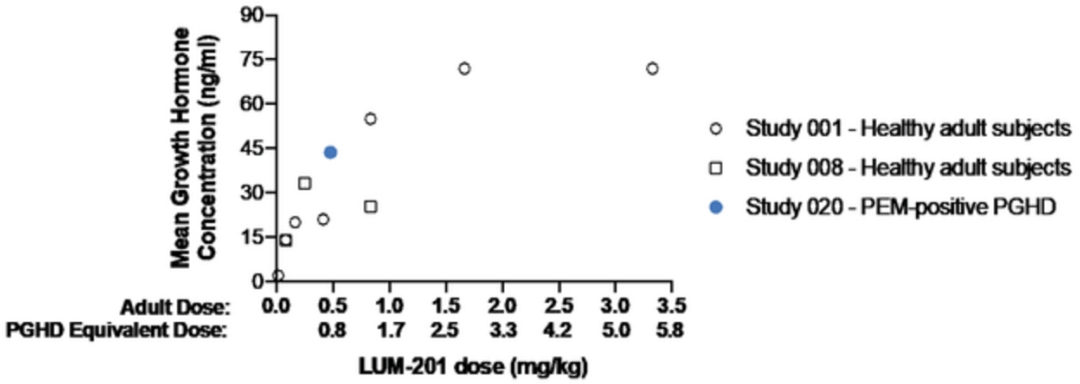


Figure 7: Mean Cmax of GH after ascending doses of LUM-201 in healthy adults and a single 0.8 mg/kg dose of LUM-201 in PGHD subjects



Clinical development plan for PGHD

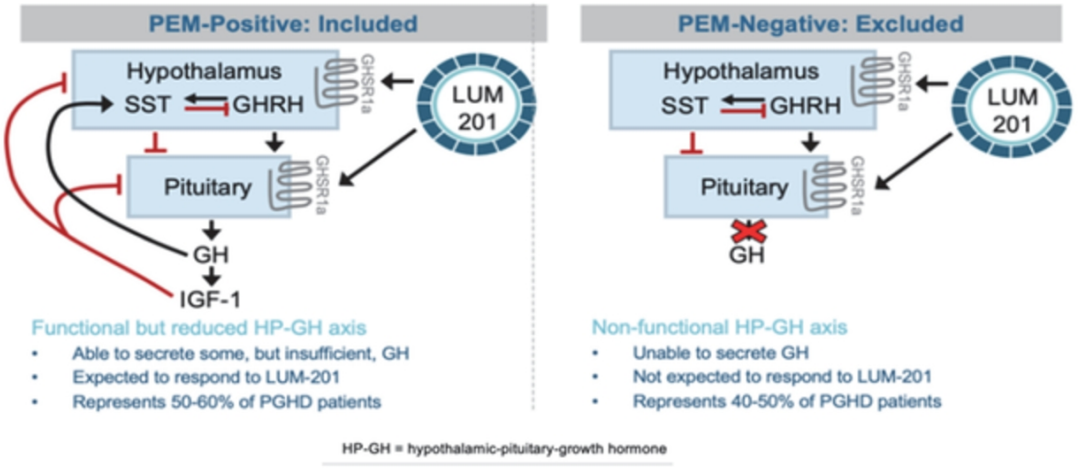
Subject to FDA review and approval of the trial, Lumos plans to start the Phase 2b Trial, six-month, open-label, parallel dosing trial of daily oral LUM-201 versus daily subcutaneous rhGH in PEM-Positive naïve-to-treatment prepubertal children with GHD by mid-2020. This proposed trial includes three dose levels of LUM-201,

0.8 mg/kg/day the highest dose tested previously in children, 1.6 mg/kg/day and 3.2 mg/kg/day, and is expected to enroll a total of 80 subjects. The final doses to be utilized in this trial will be confirmed upon receiving feedback from the FDA on Lumos' IND submission. The PK/PD analysis above, a PK simulation, and Merck's non-clinical and clinical safety data all support the choice of these doses. Once subjects finish their participation in the Phase 2b Trial they will be given the opportunity to transition to a long-term safety extension trial. The primary endpoint of the Phase 2b Trial will be annualized height velocity at six months. This trial should enable selection of an appropriate dose and calculation of the number of patients needed for the proposed follow-on pivotal trial that will assess non-inferiority. The pivotal trial will likely be a 12 month trial with a single dose cohort of oral LUM-201 compared to a control group treated with daily subcutaneous rhGH, with height velocity as the primary endpoint. In addition to these two trials, Lumos also plans to examine the safety and efficacy of LUM-201 in PEM-Positive previously rhGH treated population. During the conduct of these trials Lumos will validate the PEM strategy used to identify the responsive population.

LUM-201 addressable PGHD population

As described above not every PGHD patient has the potential to benefit from LUM-201 treatment. LUM-201 can reactivate a reduced, but intact, hypothalamic pituitary GH axis and restore growth but cannot impact a hypothalamic pituitary GH axis that is unable to produce GH upon stimulation (see Figure 8 below). Lumos believes the PEM strategy outlined above should enable prospective patient selection for upcoming trials to maximize the population that has the best chance for benefit. PGHD encompasses a range of phenotypes from severe to mild. The more severely affected patients would be the least likely to respond to LUM-201 whereas patients with a less severe phenotype would be more likely to benefit from LUM-201 treatment. Lumos believes LUM-201 treatment could address 50% to 60% of the PGHD patient population once approved. This estimate of the addressable population arises from examining existing treatment naïve and previously treated rhGH clinical trial data and available phase 4 rhGH treatment databases.

Figure 8: PEM strategy to prospectively identify LUM-201 addressable patients



Expansion of LUM-201 into Additional Endocrine Indications

There are 11 approved orphan indications for rhGH. PGHD is the first indication to assess the efficacy of LUM-201 in using Lumos' PEM strategy to select patients. If LUM-201 demonstrates the ability to increase height velocity in PEM-Positive PGHD subjects, Lumos expects to begin to explore other orphan indications for LUM-201 for which rhGH is approved using Lumos' PEM strategy to select patients. The two indications Lumos intends to pursue if LUM-201 demonstrates efficacy in PGHD patients are Turner Syndrome and SGA.

Turner Syndrome results from the complete or partial absence of one of the paired X-chromosomes in females. It is generally considered to be the most common genetic defect among females, occurring in 1:2,500 live births. Based on 1.9 million live female births per year in the United States and a prevalence of 1:2,500, there would be 760 new cases of Turner Syndrome each year and approximately 13,680 cases of Turner Syndrome, ages zero to 18.

Short stature is a cardinal feature of Turner Syndrome with adult heights generally below five feet (1.52 m) and a mean adult height of 56 inches or approximately eight inches below the mean adult female height. Daily injections of rhGH are the standard of care for growth problems in Turner Syndrome. Ovarian dysgenesis is another unifying feature in this syndrome. The expected growth spurt during puberty is generally absent. Co-administration of sex steroids and rhGH during puberty is frequently used to improve end of treatment heights.

A clinical trial exploring efficacy of LUM-201 in PEM-Positive Turner Syndrome patients is planned by Lumos after the Phase 2b Trial has yielded a dose and effect size sufficient to continue clinical development. These parameters will be used to determine doses in a Turner Syndrome trial that will explore LUM-201's effects on height velocity. Lumos believes that the oral delivery of a growth hormone secretagogue would offer advantages in this patient population. Lumos' initial estimates of the addressable population are based on using LUM-201 single dose response values seen in the previous PGHD trials (no Turner Syndrome subject has been treated with LUM-201 yet) and a smaller sample for population estimates than was used for PGHD. With these parameters, Lumos estimates that about 50% of the Turner Syndrome population should respond to LUM-201 and Lumos will further refine these estimates as it generates LUM-201 data in the Turner Syndrome population.

Using the fifth percentiles for birth weight and length as a guide, five percent to 10% of live born children can be classified as small for gestational age. Approximately 10% of these (0.5% to 1.0% of live born children) do not catch up to a normal height by their second birthday. Thus, those individuals born SGA who fail to show catch-up growth (approximately 10%) constitute a relatively high proportion of children and adults with short stature. Based on approximately 4.2 million live births per year based on the 2009 United States Census, these definitions suggest 21,000 to 42,000 pediatric subjects become eligible for treatment each year. A daily injection of rhGH is the standard of care for persistent short stature in children born with SGA.

Lumos expects that a clinical trial exploring the effect of LUM-201 on PEM-Positive patients with SGA would use results from the Phase 2b Trial to assess potentially effective doses for LUM-201 in this patient population. The trial would explore LUM-201's effects on height velocity. Lumos' initial estimates of the addressable population are based on using LUM-201 single dose response values seen in the previous PGHD trials (no SGA subject has been treated with LUM-201 yet) and a smaller sample for population estimates than was used for PGHD. With these parameters Lumos estimates that about 50% of the SGA population should respond to LUM-201 and Lumos will further refine these estimates as it generates LUM-201 data in the SGA population.

Lumos' Commercialization Strategy

Lumos intends to commercialize LUM-201 for PGHD in markets for which marketing exclusivity or patent protection can be obtained, provided it receives regulatory marketing authorization and anticipated product sales are sufficiently robust to justify the expenses required. The initial markets for LUM-201 are expected to include the United States and the European Union, which both offer marketing exclusivity for approved products in orphan diseases. Lumos has received ODD in both territories, which is one necessary component of receiving such exclusivity if approved. Lumos may also target additional markets including China and Japan. Lumos intends to seek ODD in Japan at the appropriate time. Other territories, such as China, do not offer ODD exclusivity periods. In order to protect against generic product market intrusion Lumos will seek patent protection for the use of LUM-201 in PGHD. See "— Intellectual Property" for more details.

Lumos currently has no sales, manufacturing, production or distribution capabilities. Lumos expects to enter into arrangements with third parties to manufacture, produce, market and sell LUM-201 and any other product candidates in one or multiple geographies. Lumos may not be able to enter into such arrangements with others on acceptable terms, if at all.

If one or more of Lumos' product candidates receives regulatory approval, Lumos expects to establish a specialty sales organization with technical expertise and supporting distribution capabilities to co-promote and/or commercialize its product candidates, which will be expensive and time consuming. As a company, Lumos has no prior experience in the sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including Lumos' ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, comply with regulatory requirements applicable to the marketing and sale of drug products and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of Lumos' internal sales, marketing and distribution capabilities with respect to a non-licensed product candidate would adversely impact the commercialization of LUM-201 or other product candidates.

Lumos currently has no international infrastructure including, without limitation, sales, manufacturing and distribution capabilities. Establishing and expanding commercial activities and complying with laws in foreign jurisdictions may be costly and could disrupt Lumos' operations.

Lumos may choose to work with third parties that have direct sales forces and established manufacturing, production and distribution systems, either to augment its own sales force and systems or in lieu of its own sales force and systems. If Lumos is unable to enter into such arrangements on acceptable terms or at all, it may not be able to successfully commercialize its product candidates.

Competition

The development and commercialization of new therapeutic products is highly competitive. Lumos faces competition with respect to LUM-201 and expects to face competition with respect to any product candidates that it may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market and sell rhGH therapies to Lumos' target patient group. These companies typically have a greater ability to reduce prices for their competing drugs to gain or retain market share and undermine the value proposition that Lumos might otherwise be able to offer. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for Lumos' target indications.

Lumos is developing its sole product candidate, LUM-201, for treatment of a subset of PGHD patients based on a once daily weight-based oral dosing regimen. The current standard of care for growth therapies for patients is a daily subcutaneous injection of rhGH. There are a variety of currently marketed daily rhGH therapies administered by daily subcutaneous injection and used for the treatment of GHD, principally Norditropin® (Novo Nordisk A/S), Humatrope® (Eli Lilly), Nutropin-AQ® (F. Hoffman-La Roche Ltd./Genentech, Inc.), Genotropin® (Pfizer Inc.), Saizen® (Merck Serono S.A.), Tev-tropin® (Teva Pharmaceuticals Industries Ltd.), Omnitrope® (Sandoz GmbH), Valtropin® (LG Life Science and Biopartners GmbH), and Zomacton® (Ferring Pharmaceuticals, Inc.). These rhGH drugs, apart from Valtropin, are well-established therapies and are widely accepted by physicians, patients, caregivers, third-party payors and pharmacy benefit managers, as the standard of care for the treatment of GHD. Physicians, patients, third-party payors and PBMs may not accept the addition of LUM-201 to their current treatment regimens for a variety of potential reasons, including concerns about incurring potential additional costs related to LUM-201, the perception that the use of LUM-201 will be of limited additional benefit to patients, or limited long-term safety data compared to currently available rhGH treatments.

In addition to the currently approved and marketed daily rhGH therapies, there are a variety of experimental therapies and devices that are in various stages of clinical development by companies already participating in the rhGH market as well as potential new entrants, principally Ascendis, Novo Nordisk, Genexine and OPKO (in collaboration with Pfizer).

Intellectual Property

Lumos has been assigned U.S. Patent Nos. 9763919 and 10105352, "Detecting and Treating Growth Hormone Deficiency." The patents are not due to expire in the United States before 2036 and potentially could be issued in multiple other countries for which patent applications have been filed. More specifically, related patent applications have been filed by Ammonett (such patent applications now owned by Lumos) in Australia, Brazil, Canada, China, the European Patent Office, Israel, Japan, the Republic of Korea, New Zealand, Singapore, and Ukraine. U.S. Patent Application Serial No. 16/136967 is also currently pending. The composition of matter patent for LUM-201 has expired and the chemical structure for LUM-201 is in the public domain. However, Lumos has been granted a U.S. method of use patent (and similar applications pending in other regions) directed at growth hormone deficiency disorders.

The claims of U.S. Patent Nos. 9763919 and 10105352 are directed to the use of LUM-201 (previously MK-0677) in a method of treating GH deficiency in children. The patents require patients meet certain PEMs related to a partially functioning hypothalamic-pituitary GH axis.

Lumos also has exclusive rights to a patent application PCT/US19/017964 titled “Compositions for the Treatment of NAFLD and Non-Alcoholic Steatohepatitis.” The United States application was converted to a non-provisional application in February of 2019. Lumos may elect to seek collaborations to develop LUM-201 for these indications in the future.

APA, Lumos Merck Agreement and Other Agreements

Ammonett and Lumos Merck Agreements

In July 2018, Lumos acquired any and all rights related to LUM-201 from Ammonett pursuant to the APA. Under the APA, Lumos has the obligation to use commercially reasonable efforts to develop products towards regulatory approval in specified major market countries and to commercialize each product after obtaining regulatory approval. In accordance with the APA, Lumos agreed to pay Ammonett an upfront fee of $3.5 million, development milestone payments totaling up to $17 million for achievement of specified milestones on the first LUM-201 indication that Lumos pursues and up to $14 million for achievements of specified milestones on the second LUM-201 indication that Lumos pursues, sales milestone payments totaling up to $55 million on worldwide product sales, and royalty payments based on worldwide product sales, as discussed below.

In connection with the APA, Lumos was assigned the Lumos Merck Agreement, which grants Lumos (as successor in interest to Ammonett) worldwide, exclusive, sublicensable (subject to Merck’s consent in the United States, major European countries and Japan, such consent not to be unreasonably withheld) rights under specified patents and know-how to develop, manufacture and commercialize LUM-201 for any and all indications, excluding Autism Spectrum Disorders as defined in the Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders. As part of the Lumos Merck Agreement, Merck has a co-exclusive research license with Lumos, which permits Merck certain rights, which are sublicensable, to make and use LUM-201 for research purposes, but not commercialization. Pursuant to the Lumos Merck Agreement, Lumos must notify Merck (the “Option Notice”) if it intends to enter into a development or commercial arrangement with a third party relating to products licensed under the Lumos Merck Agreement, at which time Merck will have a specified period of time to propose terms for a development or commercial arrangement and upon any exercise of such option, the parties will negotiate the terms to enter into a definitive agreement for such development or commercialization for a specified period of time. Under the Lumos Merck Agreement, Lumos is obligated to use diligence efforts to develop and commercialize licensed products in specified major market countries, including the obligation to launch a licensed product in a country within a specified time period after obtaining regulatory approval in such country.

In consideration for the rights set forth in the Lumos Merck Agreement, Merck initially received an upfront fee from Ammonett. Lumos will be required to pay Merck substantial development milestone payments for achievement of specified milestones relating to each of the first and second indications. Total potential development milestone payments are required of up to $14 million for the first LUM-201 indication that Lumos pursues and up to $8.5 million for the second LUM-201 indication that Lumos pursues. Tiered sales milestone payments totaling up to $80 million are required on worldwide net product sales up to $1 billion, and substantial royalty payments based on product sales are required if product sales are achieved.

If product sales are ever achieved, Lumos is required to make royalty payments under both the APA and the Lumos Merck Agreement collectively of 10% to 12% of total annual product net sales, subject to standard reductions for generic erosion. The royalty obligations under the Lumos Merck Agreement are on a product-by-product and country-by-country basis and will last until the later of expiration of the last licensed patent covering the product in such country and expiration of regulatory exclusivity for such product in such country. The royalty obligations under the APA are on a product-by-product and country-by-country basis for the duration of the royalty obligations under the Lumos Merck Agreement and thereafter until the expiration of the last patent assigned to Lumos under the APA covering such product in such country.

The Lumos Merck Agreement shall continue in force until the expiration of royalty obligations on a country-by-country and product-by-product basis, or unless terminated by Lumos at will by submitting 180 days’ advance written notice to Merck or by either party for the other party’s uncured material breach or specified bankruptcy events. Upon expiry of the royalty obligations the Lumos Merck Agreement converts to a fully paid-up, perpetual non-exclusive license.

If the Lumos Merck Agreement is terminated, and upon Merck’s written request, Lumos is obligated to use reasonable and diligent efforts to assign to Merck any sublicenses previously granted by Lumos.

Agreements in connection with LUM-001

In March 2012, Lumos entered into a license agreement with the University of Cincinnati primarily related to the product candidate LUM-001. Under the license agreement, LUM-001 was developed and advanced to initial clinical trials in 2016. During the conduct of the first trial a non-clinical toxicology signal was observed, leading to the voluntary halt of clinical development. In 2019, the decision was made to discontinue development of LUM-001. Lumos terminated the license agreement in October 2019. No payments were required of Lumos in connection with such termination.

Lumos conducted a natural history (non-interventional) clinical trial (NCT02931682) from 2015 to 2019, evaluating the natural course of CTD progression. In connection with this trial, Lumos entered into various clinical trial agreements ("CTAs") with sponsor sites and collaborators. In 2019, Lumos agreed to transfer responsibility for all such activities to Ultragenyx. All such CTAs and other agreements related to the trial have been transferred to Ultragenyx or terminated.

In November 2012, Lumos and certain other parties entered into a settlement agreement related to litigation with The Avicena Group, Inc. and its Chief Executive Officer related to disputes in connection with the patent for LUM-001. The settlement agreement provided that Lumos will not, among other things, develop, commercialize, market, sell, license, transfer or otherwise exploit any substance, therapeutic, diagnostic or other methodology in the dermatological field or the fields of Parkinson's, Huntington's and ALS diseases for a period of 25 years.

Manufacturing

Previously, Lumos had arrangements with third-parties for the manufacture and production of clinical supplies for LUM-001. Lumos currently does not own, nor does it plan to own, facilities for clinical or commercial manufacturing of its sole product candidate, LUM-201. Lumos has an existing supply of the LUM-201 active pharmaceutical ingredient ("API") obtained in connection with the Lumos Merck Agreement that it believes will be sufficient for its Phase 2b Trial, subject to FDA review. Lumos is in the process of performing a technology evaluation and optimization with a third-party to manufacture additional API for any further clinical trials. Lumos has an existing arrangement with a contract manufacturer to produce clinical drug product supply for the Phase 2b Trial.

Government Regulations

United States-FDA process

In the United States, the FDA regulates drugs. The Federal Food, Drug, and Cosmetic Act (the "FDCA"), and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of drugs. FDA permission to proceed under an investigational new drug ("IND") application must be obtained before clinical testing of drugs is initiated, and each clinical trial protocol for drug candidates is reviewed by the FDA prior to initiation in the United States. FDA approval also must be obtained before marketing of drugs in the United States. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, provincial, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and Lumos may not be able to obtain the required regulatory approvals.

Approval process

The FDA must approve any new drug or a drug with certain changes to a previously approved drug before a manufacturer can market it in the United States. If a company does not comply with applicable United States requirements it may be subject to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, warning or untitled letters, clinical holds, drug recalls, drug seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. The steps Lumos must complete before it can market a drug include:

- completion of preclinical laboratory tests, animal studies, and formulation studies performed in accordance with the applicable good laboratory practice ("GLP") and other regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials start; the sponsor must update the IND annually;

- approval of the trial by an IRB, or ethics committee representing each clinical site before each clinical trial begins;
- performance of adequate and well-controlled human clinical trials in accordance with applicable current good manufacturing practices ("cGMP") and current good clinical practices ("cGCP") to establish the safety and efficacy of the drug for each indication to the FDA's satisfaction;
- submission to the FDA of an NDA;
- potential review of the drug application by an FDA advisory committee, where appropriate and if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities to assess compliance with cGMP or other regulations, including licensing requirements and regulations promulgated by state regulatory authorities; and
- FDA review and approval of the NDA.

It generally takes companies many years to satisfy the FDA approval requirements, but this varies substantially based upon the type, complexity, and novelty of the drug or disease. Preclinical tests include laboratory evaluation of a drug's chemistry, formulation, and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the drug. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP. The company submits the results of the preclinical testing to the FDA as part of an IND along with other information, including information about the product drug's chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after submitting the initial IND.

The FDA requires a 30-day waiting period after the submission of each IND before the company can begin clinical testing in humans. The FDA may, within the 30-day time period, raise concerns or questions relating to one or more proposed clinical trials and place the trial on a clinical hold. In such a case, the company and the FDA must resolve any outstanding concerns before the company begins the clinical trial. Accordingly, the submission of an IND may or may not be sufficient for the FDA to permit the sponsor to start a clinical trial. The company must also make a separate submission to an existing IND for each successive clinical trial conducted during drug development.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other requirements, the sponsor must develop methods for ensuring the quality of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its labeled shelf life.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

As product candidates are developed through pre-clinical to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize products, processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause Lumos' product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of Lumos' product candidates and/or jeopardize its or its collaborators' ability to commence product sales and generate revenue.

Clinical trials

Clinical trials involve administering the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. The company must conduct clinical trials:

- in compliance with federal regulations;
- in compliance with GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors, and requirements of the IRB; as well as
- under protocols detailing the objectives of the trial, the safety monitoring parameters, and the effectiveness criteria.

The company must submit each protocol involving testing on United States patients and subsequent protocol amendments to the FDA as part of the IND application. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the sponsor is not conducting the clinical trial in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The sponsor must also submit the trial protocol and informed consent information for patients in clinical trials to an IRB for approval. An IRB may halt the clinical trial, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Companies generally divide the clinical investigation of a drug into three or four phases. While companies usually conduct these phases sequentially, they are sometimes overlapped or combined.

- *Phase 1*. The company evaluates the drug in healthy human subjects or patients with the target disease or condition. These trials typically evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the adverse events associated with increasing doses, and if possible, gain early evidence on effectiveness.
- *Phase 2*. The company administers the drug to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse events and safety risks, and preliminarily evaluate efficacy.
- *Phase 3*. The company administers the drug to an expanded patient population, generally at geographically dispersed clinical trial sites, to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug, and to provide an adequate basis for product approval.
- *Phase 4*. In some cases, the FDA may condition approval of an NDA for a drug on the company's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Lumos typically refers to such post-approval trials as Phase 4 clinical trials.

A pivotal trial is a clinical trial that adequately meets regulatory agency requirements to evaluate a drug's efficacy and safety to justify the approval of the drug. Generally, pivotal trials are Phase 3 trials, but the FDA may accept results from Phase 2 trials if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations in which there is an unmet medical need and the results are sufficiently robust.

The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, may oversee some clinical trials. This group provides authorization for whether or not a trial may move forward at designated checkpoints based on access to certain data from the trial. Lumos may also suspend or terminate a clinical trial based on evolving business objectives and the competitive climate.

Submission of an NDA

After completing the required clinical testing, Lumos can prepare and submit an NDA to the FDA, who must approve the NDA before Lumos can start marketing the drug in the United States. An NDA must include all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the drug's chemistry, manufacturing, controls, and proposed

labeling, among other things. Data can come from company-sponsored clinical trials on a drug, or from a number of alternative sources, including trials initiated by investigators. To support marketing authorization, the data Lumos submits must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug to the FDA's satisfaction.

The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual program user fees. The FDA typically increases these fees annually. ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers.

The FDA has 60 days from its receipt of an NDA to determine whether it will accept the application for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. Once the FDA accepts the filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Under the Prescription Drug User Fee Act, the FDA has a goal of responding to standard review NDAs within ten months after the 60-day filing review period, but this timeframe is often extended. The FDA reviews most applications for standard review drugs within ten to 12 months and most applications for priority review drugs within six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists.

The FDA may also refer applications for novel drugs that present difficult questions of safety or efficacy, to an advisory committee. This is typically a panel that includes clinicians and other experts that will review, evaluate, and recommend whether the FDA should approve the application. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP, and will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the drug unless compliance with cGMP is satisfactory and the NDA contains data that provide evidence that the drug is safe and effective in the indication studied.

The FDA's decision on an NDA

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter indicates that the FDA has completed its review of the application, and the agency has determined that it will not approve the application in its present form. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional clinical data and/or other significant, expensive, and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. The FDA has committed to reviewing resubmissions of the NDA addressing such deficiencies in two or six months, depending on the type of information included. Even if Lumos submits such data the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Also, the government may establish additional requirements, including those resulting from new legislation, or the FDA's policies may change, which could delay or prevent regulatory approval of Lumos' drugs under development.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for REMS can materially affect the potential market and profitability of the drug. Moreover, the FDA may condition approval on substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, the FDA may withdraw drug approvals if the company fails to comply with regulatory standards or identifies problems following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before Lumos can implement the change. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing new NDAs. As with new NDAs, the FDA often significantly extends the review process with requests for additional information or clarification.

Post-approval requirements

The FDA regulates drugs that are manufactured or distributed pursuant to FDA approvals and has specific requirements pertaining to recordkeeping, periodic reporting, drug sampling and distribution, advertising and

promotion and reporting of adverse experiences with the drug. After approval, the FDA must provide review and approval for most changes to the approved drug, such as adding new indications or other labeling claims. There also are continuing, annual user fee requirements for any marketed drugs and the establishments who manufacture its drugs, as well as new application fees for supplemental applications with clinical data.

In some cases, the FDA may condition approval of an NDA for a drug on the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Such post-approval trials are typically referred to as Phase 4 clinical trials.

Drug manufacturers are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. There are strict regulations regarding changes to the manufacturing process, and, depending on the significance of the change, it may require prior FDA approval before Lumos can implement it. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon Lumos and any third-party manufacturers that Lumos may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if a company does not comply with regulatory requirements and maintain standards or if problems occur after the drug reaches the market. If a company or the FDA discovers previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, issues with manufacturing processes, or the company's failure to comply with regulatory requirements, the FDA may revise the approved labeling to add new safety information; impose post-marketing trials or other clinical trials to assess new safety risks; or impose distribution or other restrictions under a REMS program. Other potential consequences may include:

- restrictions on the marketing or manufacturing of the drug, complete withdrawal of the drug from the market or drug recalls;
- fines, warning letters or holds on post-approval clinical trials;
- the FDA refusing to approve pending NDAs or supplements to approved NDAs, or suspending or revoking of drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of drugs that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Lumos could be subject to significant liability if we violated these laws and regulations.

Orphan drug designation

The FDA may grant ODD to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a drug receives FDA approval for the indication for which it has orphan designation, the drug may be entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the drug with orphan exclusivity.

Pediatric information

Under the Pediatric Research Equity Act (the "PREA"), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which the FDA has granted an orphan designation.

Healthcare reform

In the United States and foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of legislative and regulatory changes to the healthcare system that could affect its future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reform the way in which healthcare is funded and reduce healthcare costs. In March 2010, the PPACA was enacted, which includes measures that have significantly changed health care financing by both governmental and private insurers. The provisions of PPACA of importance to the pharmaceutical and biotechnology industry are, among others, the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% starting January 1, 2019) point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, unless the drug is subject to discounts under the 340B drug discount program;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- expansion of healthcare fraud and abuse laws, including the federal civil False Claims Act and the federal Anti-Kickback Statue, new government investigative powers and enhanced penalties for noncompliance;
- new requirements under the federal Physician Payments Sunshine Act for drug manufacturers to report information related to payments and other transfers of value made to physicians and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members; and
- new requirement to annually report certain drug samples that manufacturers and distributors provide to licensed practitioners, or to pharmacies of hospitals or other healthcare entities.

Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Although the Texas U.S. District Court Judge, as well as the presidential administration and the CMS have stated that the ruling will have no immediate effect pending appeal of the decision. On July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case.

Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance

providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the PPACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." More recently, in December 2018, CMS published a new final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment.

In addition, other health reform measures have been proposed and adopted in the United States since PPACA was enacted. For example, as a result of the Budget Control Act of 2011, as amended, providers are subject to Medicare payment reductions of two percent per fiscal year through 2027 unless additional Congressional action is taken. Further, the ATRA reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years.

More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services (the "HHS"), has already started the process of soliciting feedback on some of these measures and, at the same, is implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. While some proposed measures will require additional authorization legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In addition, certain members of Congress and the Trump Administration separately have proposed certain measures to limit drug price increases, including providing for the ability of federal government agencies to negotiate drug prices with pharmaceutical companies. Such legislation may be further considered in 2020 and years to come and impact Lumos' revenue in the future.

European Union-EMA process

In the European Union, Lumos' product candidates may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if an MA, from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization (the "ICH"), guidelines on GCP. Although the European Union Clinical Trials Directive 2001/20/EC has sought to harmonize the European Union clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the European Union Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. To improve the current system, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, which repealed Directive 2001/20/EC, was adopted on April 16, 2014 and published in the European

Official Journal on May 27, 2014. The Regulation aims at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency. Although the Regulation entered into force on June 16, 2014, it will not be applicable until six months after the full functionality of the IT portal and database envisaged in the Regulation is confirmed. This is not expected to occur until 2019. Until then the Clinical Trials Directive 2001/20/EC will still apply.

Under the current regime, before a clinical trial can be initiated it must be approved in each of the European Union Member States where the trial is to be conducted by two distinct bodies: the National Competent Authority (the "NCA"), and one or more Ethics Committees ("ECs"). Under the current regime all suspected unexpected serious adverse reactions ("SUSARs"), to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

Approval process

Under the centralized procedure, after the EMA issues an opinion, the European Commission issues a single marketing authorization valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are: derived from biotechnology processes, such as genetic engineering; contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions; and officially designated orphan drugs. For drugs that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the drug concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

There are also three other possible routes to authorize medicinal products in the European Union, which are available for products that fall outside the scope of the centralized procedure:

- National procedure. National MAs, issued by the competent authorities of the Member States of the EEA, are available however these only cover their respective territory;
- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of a medicinal product that has not yet been authorized in any European Union country; and
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Thereafter, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Lumos does not foresee that any of its current product candidates will be suitable for a National MA as they fall within the mandatory criteria for the Centralized Procedure. Therefore, Lumos' product candidates will be approved through Centralized Procedure. At the current time, it is unclear if or when a separate approval process will be needed in Great Britain, after that country exits from the European Union.

Pursuant to Regulation (EC) No 1901/2006, all applications for marketing authorization for new medicines must include the results of trials as described in a pediatric investigation plan (a "PIP"), agreed between regulatory authorities and the applicant, unless the medicine is exempt because of a deferral or waiver (e.g., because the relevant disease or condition occurs only in adults). Before the EMA is able to begin its assessment of a centralized procedure MA application, it will validate that the applicant has complied with the agreed pediatric investigation plan. The applicant and the EMA may, where such a step is adequately justified, agree to modify a pediatric investigation plan to assist validation. Modifications are not always possible; it may take longer to agree than the period of validation permits; and may still require the applicant to withdraw its MAA, and to conduct additional non-clinical and clinical trials. Products that are granted an MA on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Orphan drug designation

In the European Union, Regulation (EC) No 141/2000, as amended, states that a drug will be designated as an orphan drug if its sponsor can establish:

- that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment; and
- that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, that the drug will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a drug as an orphan drug. An application for the designation of a drug as an orphan drug must be submitted at any stage of development of the drug before filing of an MA application.

If a centralized procedure MA in respect of an orphan drug is granted pursuant to Regulation (EC) No 726/2004, regulatory authorities will not, for a period of usually 10 years, accept another application for an MA, or grant an MA or accept an application to extend an existing MA, for the same therapeutic indication, in respect of a similar drug. This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the drug concerned, that the criteria for ODD are no longer met, in other words, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. The exclusivity period may increase to 12 years if, among other things, the MAA includes the results of trials from an agreed pediatric investigation plan. Notwithstanding the foregoing, an MA may be granted for the same therapeutic indication to a similar drug if:

- the holder of the MA for the original orphan drug has given its consent to the second applicant;
- the holder of the MA for the original orphan drug is unable to supply sufficient quantities of the drug; or
- the second applicant can establish in the application that the second drug, although similar to the orphan drug already authorized, is safer, more effective or otherwise clinically superior.

Regulation (EC) No 847/2000 lays down definitions of the concepts ‘similar drug’ and ‘clinical superiority.’ Other incentives available to orphan drugs in the European Union include financial incentives such as a reduction of fees or fee waivers and protocol assistance. ODD does not shorten the duration of the regulatory review and approval process.

Good manufacturing practices

Like the FDA, the EMA, the competent authorities of the European Union Member States and other regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacturing of drugs prior to approving a drug.

If, after receiving clearance from regulatory agencies, a company makes a material change in manufacturing equipment, location, or process, additional regulatory review and approval may be required. Once Lumos or Lumos’ partners commercialize drugs, Lumos will be required to comply with cGMP, and drug-specific regulations enforced by the European Commission, the EMA and the competent authorities of European Union Member States following drug approval. Also like the FDA, the EMA, the competent authorities of the European Union Member States and other regulatory agencies also conduct regular, periodic visits to reinspect equipment, facilities, and processes following the initial approval of a drug. If, as a result of these inspections, the regulatory agencies determine that Lumos or its partners’ equipment, facilities, or processes do not comply with applicable regulations and conditions of drug approval, they may seek civil, criminal or administrative sanctions and/or remedies against Lumos, including the suspension of its manufacturing operations or the withdrawal of Lumos’ drug from the market.

Post-approval controls

The holder of a European MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAAs must include a risk management plan (an "RMP"), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under European Union directives, the details are governed by regulations in each European Union Member State and can differ from one country to another.

Data and market exclusivity

Similar to the United States, there is a process to authorize generic versions of innovative drugs in the European Union. Generic competitors can, where data exclusivity has expired, submit abridged applications to authorize generic versions of drugs authorized by EMA through a centralized procedure referencing the innovator's data and demonstrating bioequivalence to the reference drug, among other things. If a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved. This system is usually referred to as "8+2". There is also a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Other international markets-drug approval process

In some international markets (such as China or Japan), although data generated in United States or European Union trials may be submitted in support of a marketing authorization application, regulators may require additional clinical trials conducted in the host territory, or studying people of the ethnicity of the host territory, prior to the filing or approval of marketing applications within the country.

Pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drugs for which we may obtain regulatory approval. In the United States and markets in other countries, sales of any drugs for which we receive regulatory approval for commercial sale will depend on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug may be separate from the process for setting the reimbursement rate that the payor will pay for the drug. Third-party payors may limit coverage to specific drugs on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Moreover, a payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Additionally, coverage and reimbursement for drugs can differ significantly from payor to payor. One third-party payor's decision to cover a particular drug does not ensure that other payors will also provide coverage for the drug, or will provide coverage at an adequate reimbursement rate. Adequate third-party reimbursement may not be available to enable Lumos to maintain price levels sufficient to realize an appropriate return on its investment in drug development.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of drugs and services, in addition to their safety and efficacy. To obtain coverage and reimbursement for any drug that might be approved for sale, Lumos may need to conduct expensive pharmacoeconomic trials to demonstrate the medical necessity and cost-effectiveness of its drug. These trials will be in addition to the trials required to obtain regulatory approvals. If third-party payors do not consider a drug to be cost-effective compared to other available therapies, they may not cover the drug after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its drugs at a profit.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs for branded prescription drugs. By way of example, PPACA contains provisions that may reduce the profitability of drugs, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for Lumos' drugs.

In the European Community, governments influence the price of drugs through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those drugs to consumers. Some jurisdictions operate positive and negative list systems under which drugs may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new drugs. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any drugs for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. In addition, the focus on cost containment measures in the United States and other countries has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if Lumos attains favorable coverage and reimbursement status for one or more drugs for which Lumos receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other healthcare laws impacting sales, marketing, and other company activities

Numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the HHS, the U.S. Department of Justice, and similar foreign, state, and local government authorities, regulate and enforce laws and regulations applicable to sales, promotion and other activities of pharmaceutical manufacturers. These laws and regulations may impact, among other things, Lumos' clinical research programs, proposed sales and marketing and education activities, and financial and business relationships with future prescribers of Lumos' product candidates, once approved. These laws and regulations include U.S. federal, U.S. state and foreign anti-kickback, false claims, and data privacy and security laws, which are described below, among other legal requirements that may affect Lumos' current and future operations.

The FDA regulates all advertising and promotion activities for drugs under its jurisdiction both prior to and after approval. Only those claims relating to safety and efficacy that the FDA has approved may be used in labeling once the drug is approved. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those Lumos tested and the FDA approved. Such off-label uses are common across medical specialties, and often reflect a physician's belief that the off-label use is the best treatment for the patients. The FDA does not regulate the behavior of physicians in their choice of treatments, but FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. If Lumos does not comply with applicable FDA requirements Lumos may face adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA. Promotion of off-label uses of drugs can also implicate the false claims laws described below.

Anti-kickback laws including, without limitation, the federal Anti-Kickback Statute that applies to items and services reimbursable under governmental healthcare programs such as Medicare and Medicaid, make it illegal for a person or entity to, among other things, knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, to induce, or in return for, purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service reimbursable, in whole or in part, under a federal healthcare program. Due to the breadth of the statutory provisions, limited statutory exceptions and regulatory safe harbors, and the scarcity of guidance in the form of regulations, agency advisory opinions, sub-regulatory guidance and judicial decisions addressing industry practices, it is possible that Lumos' practices might be challenged under anti-kickback or similar laws. Moreover, recent healthcare reform legislation has strengthened these laws. For example, PPACA among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statute to clarify that a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a crime. In addition, PPACA clarifies that the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

False claims laws, including, without limitation, the federal civil False Claims Act, prohibit, among other things, anyone from knowingly and willingly presenting, or causing to be presented for payment, to the federal government (including Medicare and Medicaid) claims for reimbursement for, among other things, drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Lumos' activities relating to the sales and marketing of its drugs may be subject to scrutiny under these laws, as well as civil monetary penalties laws and the criminal healthcare fraud provisions enacted as part of HIPAA.

HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (the "HITECH"), and its implementing regulations governs the conduct of certain electronic healthcare transactions and imposes requirements with respect to safeguarding the security and privacy of protected health information on HIPAA covered entities and their business associates who provide services involving HIPAA protected health information to such covered entities.

The federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members.

In addition, Lumos may be subject to state law equivalents of each of the above federal laws, such as anti-kickback, self-referral, and false claims laws which may apply to Lumos' business practices, including but not limited to, research, distribution, sales and marketing arrangements and submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical manufacturers to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers; state laws that require pharmaceutical manufacturers to file reports with states regarding drug pricing and/or marketing information, such as the tracking and reporting of gifts, compensation and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Violations of these laws may result in criminal, civil and administrative sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid),

disgorgement, contractual damages, reputational harm and the imposition of corporate integrity agreements or other similar agreements with governmental entities, which may impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as individual imprisonment, also can be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called "responsible corporate officer" doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing. Given the significant penalties and fines that can be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions and additional corporate integrity obligations. If the government were to allege or convict Lumos or Lumos' executive officers of violating these laws, Lumos' business could be harmed.

Similar rigid restrictions are imposed on the promotion and marketing of drugs in the European Union and other countries. Even in those countries where we may not be directly responsible for the promotion and marketing of Lumos' drugs, if Lumos' potential international distribution partners engage in inappropriate activity it can have adverse implications for Lumos.

Legal Proceedings

Lumos is not currently a party to any material legal proceedings. From time to time, Lumos may be involved in various claims and legal proceedings relating to its operations. Regardless of outcome, litigation can have an adverse impact on Lumos because of defense and settlement costs, diversion of management resources and other factors.

Facilities

Lumos' corporate headquarters are in Austin, Texas, where it occupies approximately 5,000 square feet of office space under a lease expiring on November 1, 2021. Lumos believes its existing facilities meet its current needs and Lumos has convenient access to additional space for its future needs.

Employees

As of September 30, 2019, Lumos had seven full-time employees, and no part-time employees, as well as five regularly engaged consultants. None of Lumos' employees are represented by any collective bargaining agreements. Lumos believes that it maintains good relations with its employees.

NEWLINK'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

For NewLink's management's discussion and analysis of financial condition and results of operations, please refer to "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" set forth in NewLink's Annual Report on Form 10-K for the year ended December 31, 2018, included as Annex B to this proxy statement, and "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations" set forth in NewLink's Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2019, June 30, 2019 and September 30, 2019, included as Annex C, Annex D and Annex E to this proxy statement, which sections are incorporated by reference herein.

LUMOS' MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of financial condition and results of operations should be read together with the "Unaudited Pro Forma Condensed Combined Financial Information" and the financial statements of Lumos and accompanying notes, each appearing elsewhere in this proxy statement. This discussion of Lumos' financial condition and results of operations contains certain statements that are not strictly historical and are "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve a high degree of risk and uncertainty. Actual results may differ materially from those projected in the forward-looking statements due to other risks and uncertainties that exist in Lumos' operations, development efforts and business environment, including those set forth in the section titled "Risk Factors—Risks Related to the Operation of Lumos' Business" in this proxy statement, the other risks and uncertainties described in the section titled "Risk Factors" in this proxy statement and the other risks and uncertainties described elsewhere in this proxy statement. All forward-looking statements included in this proxy statement are based on information available to Lumos as of the date hereof, and Lumos assumes no obligation to update any such forward-looking statement.

Overview

Lumos is a clinical-stage biopharmaceutical company focused on the identification, acquisition and in-license, development, and commercialization of novel products for the treatment of rare diseases. Lumos' mission is to develop new therapies for people with rare diseases, prioritizing its focus where the medical need is high, and the pathophysiology is clear. Lumos is committed to this mission and a strategy that is grounded upon time and cost-efficient drug development for Lumos to develop and deliver safe and effective therapies to patients. Driven by a sense of commitment to rare disease patients, their families and the rare disease community, the goal of Lumos is to be a leading rare disease drug company.

The current Lumos pipeline is focused on the development of an orally administered small molecule, the GH secretagogue LUM-201, for three rare endocrine disorders. A secretagogue is a substance that stimulates the secretion or release of another substance. LUM-201 stimulates the release of GH and is referred to as a GH secretagogue. The current targeted indications for LUM-201 are PGHD, Turner Syndrome and SGA, in each case in a certain subset of affected patients. Lumos is planning to initiate a clinical development program to study the effects of LUM-201 in PGHD in mid-2020 with a Phase 2b Trial. Depending on the outcome of data developed in the Phase 2b Trial and the timing of such data, Lumos plans to conduct Phase 2 clinical trials to study the effects of LUM-201 for Turner Syndrome and SGA in a certain subset of affected patients.

If approved, LUM-201 has the potential to become the first approved oral GH secretagogue to treat rare endocrine disorders associated with GH deficiencies, starting with PGHD, providing an alternative to the current standard regimen of daily injections. Lumos acquired LUM-201 from Ammonett in July 2018. LUM-201 received the ODD in the United States and the European Union for GHD in 2017. The United States patent "Detecting and Treating Growth Hormone Deficiency" has been issued with an expiration in 2036. Other patent applications are pending in multiple jurisdictions.

Since its inception, Lumos' operations have focused on organizing and staffing, business planning, raising capital, acquiring its technology and assets, and conducting preclinical and clinical development of its product candidates. Lumos has devoted substantial effort and resources to acquiring its current product candidate, LUM-201, as well as its previous product candidate, LUM-001, which it ceased developing in 2019. Lumos acquired LUM-201 through its acquisition of substantially all of the assets related to LUM-201 from Ammonett which had licensed LUM-201 in July 2018 from Merck. Lumos does not have any product candidates approved for sale and has not generated any revenue from product sales. Lumos has funded its operations primarily through the sale and issuance of preferred stock, as well as through in-kind support pursuant to a collaborative research and development agreement with the NIH from 2012 to April 2019.

Since inception, Lumos has incurred significant operating losses and negative operating cash flows and there is no assurance that it will ever achieve or sustain profitability. Lumos' net losses were $7.3 million, $9.5 million, $11.2 million, and $8.9 million for the nine months ended September 30, 2019 and 2018 and the years ended December 31, 2018 and 2017, respectively. As of September 30, 2019, Lumos had an accumulated deficit of $56.5 million. Lumos expects to continue to incur significant expenses and increasing operating losses for the foreseeable future. Lumos anticipates that its expenses will increase significantly in connection with its ongoing activities as Lumos:

- continues the ongoing and planned clinical development of LUM-201;
- hires additional administrative, clinical, regulatory and scientific personnel;
- initiates preclinical studies and clinical trials for any additional indications for its current product candidates and any future product candidates that Lumos may pursue;
- builds a portfolio of product candidates through the acquisition or in-license of drugs or product candidates and technologies;
- develops, maintains, expands, and protects its intellectual property portfolio;
- manufactures, or has manufactured, clinical and commercial supplies of its product candidates;
- seeks marketing approvals for its current and future product candidates that successfully complete clinical trials;
- establishes a sales, marketing and distribution infrastructure to commercialize any product candidate for which Lumos may obtain marketing approval; and
- incurs additional costs associated with operating as a public company following the completion of this Merger.

Recent Events

On September 30, 2019, NewLink, Merger Sub and Lumos entered into a Merger Agreement pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Lumos, with Lumos continuing as a wholly-owned subsidiary of NewLink. Following the Merger, NewLink will be renamed Lumos Pharma, Inc.

Subject to the terms and conditions of the Merger Agreement, at the Effective Time, (a) each outstanding share of Lumos capital stock will be converted into the right to receive a number of shares of NewLink's common stock equal to the applicable exchange ratio; and (b) each outstanding Lumos stock option that has not previously been exercised prior to the Effective Time will be assumed by NewLink and converted into an option to purchase shares of NewLink's common stock, with the number of NewLink's shares subject to such option and the exercise price being appropriately adjusted to reflect the Common Stock Exchange Ratio.

The Merger is intended to qualify for the United States federal income tax purposes as a reorganization under the provisions of Section 368(a) of the Code.

The Merger Agreement contains certain termination rights for both NewLink and Lumos, and further provides that, upon termination of the Merger Agreement under certain circumstances, the terminating party, whether NewLink or Lumos, will be required to pay a termination fee of $2.0 million.

Components of Results of Operations

Research and development expense

Research and development expenses for the current year consist primarily of costs incurred in connection with the development of Lumos' current product candidate, LUM-201. Lumos expenses research and development costs as incurred. These expenses include:

- costs of funding research performed by third parties, including pursuant to agreements with CROs, as well as investigative sites and consultants that conduct Lumos' preclinical studies and clinical trials;
- expenses incurred under agreements with CMOs, including manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical study and clinical trial materials;

- payments made under Lumos' third-party licensing agreements, other than amounts classified as acquired in-process research and development expenses;
- personnel costs for Lumos employees involved in the research and development activities;
- consultant fees and expenses associated with outsourced professional scientific development services; and
- expenses for regulatory activities, including filing fees paid to regulatory agencies.

Milestone payment obligations incurred prior to regulatory approval of a product candidate, which are accrued when the event requiring payment of the milestone occurs will be included in research and development expense.

Lumos typically uses its employee, consultant, and infrastructure resources across its development programs. Lumos tracks certain outsourced development costs by product candidate but does not allocate all personnel costs or other internal costs to specific product candidates.

Lumos expects its research and development expense will increase for the foreseeable future as it seeks to advance development of LUM-201. The successful development of LUM-201 is highly uncertain. At this time, Lumos cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of LUM-201. Lumos is also unable to predict when, if ever, material net cash inflows may commence from sales of LUM-201 or any future product candidates Lumos may develop due to numerous factors, including, among others:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the duration of patient follow-up and number of patient visits;
- the results of Lumos' clinical trials;
- the securing of commercial manufacturing capabilities.
- the receipt of marketing approvals; and
- the commercialization of product candidates.

Lumos may never succeed in obtaining regulatory approval for LUM-201 or any future product candidates. Lumos costs will increase as product candidates advance to later stages of clinical development, since later stage products generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

Acquired in-process research and development expense

Acquired in-process research and development expense consists of the initial up-front payments incurred in connection with the acquisition or licensing of product candidates that do not meet the definition of a business under ASC 805, *Business Combinations*. Lumos' acquired in-process research and development expense reflects the cash consideration paid up front in Lumos' acquisition of Ammonett assets related to LUM-201 in July 2018.

General and administrative expense

General and administrative expense consists primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for employees in executive, finance, accounting, business development, legal and human resource functions. General and administrative expense also includes corporate facility costs, including rent, utilities, depreciation, and maintenance, not otherwise included in research and development expense, as well as legal fees related to intellectual property and corporate matters and fees for accounting, recruiting and consulting services.

Lumos anticipates that its general and administrative expense will increase as a result of increased headcount, expanded infrastructure and higher accounting, legal, consulting, and investor relations fees, as well as increased director and officer insurance premiums, associated with being a public company. Lumos also anticipates that its general and administrative expense will increase as it supports clinical trials for LUM-201. In addition, if and when Lumos believes that regulatory approval of LUM-201 appears likely, Lumos anticipates an increase in headcount and expense as a result of its preparation for commercial operations.

Results of operations

The following table sets forth Lumos selected statements of operations data for the periods indicated (in thousands):

	Nine months ended September 30, (unaudited)		Years ended December 31,	
	2019	2018	2018	2017
Operating expenses:				
Research and development	$ 4,538	$ 4,126	$ 5,253	$ 6,321
Acquired in-process research and development	—	3,500	3,500	—
General and administrative	2,893	1,917	2,533	2,676

Loss from operations

(7,431
)

(9,543
)

(11,286
)

(8,997
)

Other income (net):

Interest and other income, net

88

89

124

51

Net loss
$
(7,343
)
$
(9,454
)
$
(11,162
)
$
(8,946
)

Comparison of the nine months ended September 30, 2019 and 2018

Research and development expense

Research and development expense increased by $0.4 million to $4.5 million for the nine months ended September 30, 2019 from $4.1 million for the nine months ended September 30, 2018. The following table summarizes Lumos' research and development expenses for the nine months ended September 30, 2019 and 2018:

	Nine months ended September 30, (unaudited)	
	2019	2018
	(in thousands)	

Preclinical and clinical development expense	$	3,213	$	2,825
Compensation expense		1,174		1,175
Other expenses		151		126
Total research and development expense	$	4,538	$	4,126

The increase in total research and development expense of $0.4 million is primarily due to a $0.4 million increase in LUM-201 preclinical and clinical expense.

General and administrative expense

General and administrative expense increased by $1.0 million to $2.9 million for the nine months ended September 30, 2019 from $1.9 million for the nine months ended September 30, 2018. The increase was primarily due to increased legal and professional fees relating to the Merger. The following table summarizes Lumos' general and administrative expenses for the nine months ended September 30, 2019 and 2018:

	Nine months ended September 30, (unaudited)	
	2019	**2018**
	(in thousands)	
Compensation expense, other than stock-based compensation	$ 632	$ 632
Professional and legal expense	1,154	365
Stock-based compensation expense	132	151
Other expenses	974	770
Total general and administrative expense	$ 2,893	$ 1,917

Comparison of the years ended December 31, 2018 and 2017

Research and development expense

Research and development expense decreased by $1.0 million to $5.3 million for the year ended December 31, 2018 from $6.3 million for the year ended December 31, 2017. The following table summarizes Lumos' research and development expenses for the years ended December 31, 2018 and 2017:

	Years ended December 31	
	2018	2017
	(in thousands)	
Preclinical and clinical development expense	$ 3,579	$ 3,800
Compensation expense	1,509	2,347
Other expenses	165	174
Total research and development expense	$ 5,253	$ 6,321

The decrease in total research and development expense reflected a $0.8 million decrease in compensation costs, as well as a $0.2 million decrease in preclinical and clinical expense, primarily related to scaling back the LUM-001 program, and a related reduction in force at the end of 2017.

Acquired-in-process research and development

The cash consideration paid up front to acquire the assets, primarily LUM-201 from Ammonett in July 2018, was $3.5 million. Lumos incurred no acquired in-process research and development expense in 2017.

General and administrative expense

General and administrative expense decreased by $0.1 million to $2.5 million for the year ended December 31, 2018 from $2.7 million for the year ended December 31, 2017. The decrease was primarily due to reduction of force at the end of 2017 due to scaling back the LUM-001 program. The following table summarizes Lumos' research general and administrative expenses for the years ended December 31, 2018 and 2017:

	Years ended December 31	
	2018	2017
	(in thousands)	
Compensation expense, other than stock-based compensation	$ 812	$ 1,104
Professional and legal expense	724	561
Stock-based compensation expense	199	187
Other expense	797	823
Total general and administrative expense	$ 2,533	$ 2,676

Liquidity and Capital Resources

The following table shows a summary of Lumos' cash flows for the periods indicated:

	Nine months ended September 30, (unaudited)		Years ended December 31,	
	2019	2018	2018	2017
	(in thousands)			
Net cash (used in) operating activities	$ (6,357)	$ (5,226)	$ (7,190)	$ (9,384)
Net cash (used in) investing activities	—	(3,502)	(3,501)	(4)
Net cash provided by financing activities	—	34	34	—
Net (decrease) in cash	$ (6,357)	$ (8,694)	$ (10,657)	$ (9,388)

Sources of funds

Lumos has funded its operations primarily through the sale and issuance of preferred stock as well as through in-kind support pursuant to a collaborative research and development agreement with the NIH. As of September 30, 2019, Lumos had $7.7 million in cash and cash equivalents and an accumulated deficit of $56.5 million.

Uses of funds

Operating activities

During the nine months ended September 30, 2019, Lumos used $6.4 million of cash in operating activities. Cash used in operating activities reflected Lumos' net loss of $7.3 million, offset by a net change in its operating assets and liabilities of $0.8 million and non-cash charges of $0.2 million mainly related to stock-based compensation. The net change in Lumos' operating assets and liabilities is primarily attributable to the increase in accrued liabilities and accounts payable due to the timing of payments to its vendors.

During the nine months ended September 30, 2018, Lumos used $5.2 million of cash in operating activities. Cash used in operating activities reflected Lumos' net loss of $9.5 million, offset by a net change in its operating assets and liabilities of $0.6 million and non-cash charges of $3.7 million primarily related to the expensing of the in-process research and development acquired and stock-based compensation. The net change in Lumos' operating assets and liabilities is primarily attributable to the increase in accrued liabilities and accounts payable due to the timing of payments to its vendors. Cash used for investing changed primarily due to the $3.5 million of cash paid to acquire in-process research and development.

During the year ended December 31, 2018, Lumos used $7.2 million of cash in operating activities. Cash used in operating activities reflected Lumos' net loss of $11.1 million, offset by a net decrease in operating assets and liabilities of $0.2 million and non-cash charges of $3.7 million, primarily related to the expensing of the in-process research and development acquired and stock-based compensation. The net change in Lumos' operating assets and liabilities is primarily attributable to the increase in accrued liabilities and accounts payable due to the timing of payments to its vendors. Cash used for investing changed primarily due to the $3.5 million of cash paid to acquire in-process research and development.

During the year ended December 31, 2017, Lumos used $9.4 million of cash in operating activities. Cash used in operating activities reflected Lumos net loss of $8.9 million, and a net increase in operating assets and liabilities of $0.7 million, and offset by non-cash charges of $0.2 million, principally related to stock-based compensation. The net change in Lumos' operating assets and liabilities is primarily attributable to the decrease in accrued liabilities and accounts payable due to the timing of payments to its vendors.

Funding requirements

Lumos expects its expenses to increase in connection with its ongoing activities, particularly as Lumos continues the research and development of, continues or initiates clinical trials of, and seeks marketing approval for, its product candidate, LUM-201. In addition, if Lumos obtains marketing approval for LUM-201, Lumos expects to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Furthermore, following the completion of the Merger, Lumos expects to incur additional costs associated with operating as a public company. Accordingly, Lumos will need to obtain substantial additional funding in connection with its continuing operations. If Lumos is unable to raise capital when needed or on attractive terms, Lumos would be forced to delay, reduce or eliminate its research and development programs or future commercialization efforts.

Lumos believes its cash at September 30, 2019 combined with NewLink's existing cash to be consolidated with Lumos' at the closing of the Merger, will be sufficient to fund Lumos' current operating plans through the readout of the planned Phase 2b Trial.

Lumos' future capital requirements will depend on many factors, including:

- the scope, progress, results, and costs of preclinical studies and clinical trials;
- the scope, prioritization, and number of Lumos' research and development programs;
- the costs, timing, and outcome of regulatory review of LUM-201 or any future product candidate;
- Lumos' ability to establish and maintain collaborations on favorable terms, if at all;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing Lumos' intellectual property rights, and defending intellectual property-related claims;
- the extent to which Lumos acquires or in-licenses other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if Lumos obtains regulatory approvals to market its product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and Lumos may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, LUM-201, if approved, may not achieve commercial success. Lumos' commercial revenues, if any, will be derived from sales of LUM-201 that Lumos does not expect to be commercially available for many years, if at all. Accordingly, Lumos will need to continue to rely on additional financing to achieve its business objectives. Adequate additional financing may not be available to Lumos on acceptable terms, or at all.

Until such time, if ever, as Lumos can generate substantial product revenues, Lumos expects to finance its cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that Lumos raises additional capital through the sale of equity or convertible debt securities, the ownership interests of its stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting Lumos' ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If Lumos raises funds through additional collaborations, strategic alliances or licensing arrangements with third parties, Lumos may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to Lumos. If Lumos is unable to raise additional funds through equity or debt financings when needed, Lumos may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market product candidates that Lumos would otherwise prefer to develop and market itself.

Contractual Obligations and Commitments

The following table summarizes Lumos' commitments to settle contractual obligations at December 31, 2018:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
(in thousands)					
Operating leases[1]	$ 196	$ 399	—	—	$ 595
Total	$ 196	$ 399	—	—	$ 595

—

—

$

595

(1) Reflects obligations pursuant to Lumos' office lease in Austin, TX.

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. The table does not include obligations under agreements that Lumos can cancel without a significant penalty.

Off-Balance Sheet Arrangements

Lumos does not have any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. Lumos does not engage in off-balance sheet financing arrangements. In addition, Lumos does not engage in trading activities involving non-exchange traded contracts. Lumos therefore believes that it is not materially exposed to any financing, liquidity, market or credit risk that could arise if it had engaged in these relationships.

Critical Accounting Policies

Lumos' financial statements are prepared in accordance with GAAP. The preparation of Lumos' financial statements requires Lumos to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reported period. Lumos bases its estimates on historical experience, known trends and events and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Lumos evaluates its estimates and assumptions on an ongoing basis. Lumos' actual results may differ from these estimates under different assumptions and conditions.

While Lumos' significant accounting policies are described in more detail in the notes to its financial statements appearing elsewhere in this proxy statement, Lumos believes that the following accounting policies are those most critical to the preparation of its financial statements.

Asset acquisitions

Accounting for transactions as asset acquisitions is significantly different than business combinations. For example, acquired in-process research and development is expensed for asset acquisitions and capitalized for business combinations. Goodwill is only recognized in business combination transactions. The fair value of contingent consideration is recognized in business combination transactions and may be recognized in asset acquisitions if payment is probable and the amount can be estimated. As a result, it is important to determine whether a business or an asset or a group of assets is acquired. A business is defined in ASC 805, *Business Combinations*, as an integrated set of inputs and processes that can generate outputs that have the ability to provide a return to its investors or owners. Typical inputs include long-lived assets (including intangible assets or rights to use long-lived assets), intellectual property and the ability to obtain access to required resources. Typical processes include strategic, operational and resource management processes that are typically documented or evident through an organized workforce.

In January 2017, FASB issued ASU 2017-01, *Clarifying the Definition of a Business* ("ASU 2017-01"). A key provision within ASU 2017-01 is the single or similar asset threshold. When substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the acquired set is not a business. Lumos adopted this standard effective January 1, 2018.

Lumos considered all of the above factors when determining whether a business was acquired. In evaluating Lumos' acquisition of substantially all the assets of Ammonett, Lumos concluded virtually all the value was concentrated in the acquired LUM-201 program. As such, Lumos accounted for the transaction as an asset acquisition. The fair value, represented by the up-front cash payment, allocated to the acquired LUM-201 development program was expensed and not capitalized.

Research and development expenses

Research and development expenses consist primarily of costs incurred in connection with the development of Lumos' product candidates. Lumos expenses research and development costs as incurred.

Acquired in-process research and development

Acquired in-process research and development expense consists of the initial up-front payments incurred in connection with the acquisition or licensing of product candidates that do not meet the definition of a business under ASC 805, *Business Combinations*.

Stock-based compensation

Lumos measures expense for all stock options based on the estimated fair value of the award on the grant date. Lumos uses the Black-Scholes option pricing model to value its stock option awards. Lumos recognizes compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Lumos has not issued awards where vesting is subject to a market or performance condition; however, if Lumos were to grant such awards in the future, recognition would be based on the derived service period. Expense for awards with performance conditions would be estimated and adjusted on a quarterly basis based upon Lumos' assessment of the probability that the performance condition will be met.

Estimating the fair value of options requires the input of subjective assumptions, including the estimated fair market value of Lumos' common stock, the expected life of the option, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in Lumos' Black-Scholes option-pricing model represent management's best estimates and involve several variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, Lumos' stock-based compensation expense could be materially different in the future.

There assumptions are estimated as follows:

- *Expected Term.* The expected term represents the period that Lumos' stock options are expected to be outstanding. Lumos calculated the expected term using the simplified method based on the average of each option's vesting term and the contractual period during which the option can be exercised, which is typically 10 years following the date of grant.
- *Expected Volatility.* The expected volatility was based on the historical stock volatility of several of Lumos' comparable publicly traded companies over a period of time equal to the expected term of the options, as it does not have any trading history to use the volatility of Lumos' own common stock.
- *Risk-Free Interest Rate.* The-risk-free interest rate was based on the yields of U.S. Treasury securities with maturities appropriate for the term of the award.
- *Expected Dividend Yield.* Lumos has not paid dividends on its common stock nor does it expect to pay dividends in the foreseeable future.
- *Fair Market Value of Common Stock.* As Lumos' common stock has not historically been publicly traded, Lumos has periodically estimated the fair market value of common stock. See "—Fair market value of common stock."

The following table reflects the weighted average assumptions used to estimate the fair value of options granted in the years ended December 31, 2018 and December 31, 2017.

	Years ended December 31	
	2018	**2017**
Expected term (in years)	5.92	6.08
Expected volatility	90%	90%
Risk-free interest rate	2.8%	2.1%
Expected dividend yield	0%	0%
Fair market value of common stock	$0.24	$0.32

Fair market value of common stock

Historically, for all periods prior to the Merger, the fair market values of the shares of common stock underlying Lumos' stock options were estimated on each grant date by the Lumos Board. In order to determine the fair market value of Lumos' common stock, the Lumos Board considered, among other things,

contemporaneous valuations of its common and preferred stock prepared by unrelated third-party valuation firms in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* ("Practice Aid"). Given the absence of a public trading market of Lumos' capital stock, the Lumos Board exercised reasonable judgment and considered several objective and subjective factors to determine the best estimate of the fair market value of Lumos' common and preferred stock, including:

- contemporaneous third-party valuations of Lumos' common stock;
- the prices, rights, preferences, and privileges of Lumos' preferred stock relative to the common stock;
- Lumos' business, financial condition, and results of operations, including related industry trends affecting Lumos' operations;
- the likelihood of achieving a liquidity event, such as an IPO or sale of the company, given prevailing market conditions;
- the lack of marketability of Lumos' common stock;

- the market performance of comparable publicly traded companies; and
- United States and global economic and capital market conditions and outlook.

There are significant judgments and estimates inherent in the determination of these valuations. These judgments and estimates include assumptions regarding Lumos' future performance, including the successful completion of its clinical trials and the time to liquidity, as well as the determination of the appropriate valuation methods at each valuation date. If Lumos had made different assumptions, its valuation could have been different. The foregoing valuation methodologies are not the only methodologies available, and they will not be used to value the combined company's common stock if the Merger is completed. Accordingly, stockholders and investors should not place undue reliance on the foregoing valuation methodologies as an indicator of the combined company's future stock price.

Under the Merger Agreement, at the Effective Time, each Lumos option outstanding and unexercised as of immediately prior to the Effective Time, whether or not vested, shall be assumed by NewLink and converted into and become an option to purchase shares of NewLink's common stock. Following the closing, the fair market value of such options will be determined based on the closing price of NewLink common stock on Nasdaq.

Recent Accounting Pronouncements

See Notes 2 and 3 to Lumos' financial statements beginning on page F-7 of this proxy statement for a description of recent accounting pronouncements applicable to its financial statements.

MANAGEMENT FOLLOWING THE MERGER

Executive Officers and Directors

Pursuant to the Merger Agreement, immediately after the Effective Time, the combined company's board of directors will be fixed at seven members, three of whom will be directors designated by NewLink, three of whom will be directors designated by Lumos, and one board seat will initially be vacant. Following the Merger, the seventh board member will be designated by the board of directors of the combined company. Designees to the board of directors are expected to satisfy the requisite independence requirements for the NewLink Board, as well as the sophistication and independence requirements for committee members pursuant to Nasdaq listing requirements. It is anticipated that the NewLink designees will be Thomas A. Raffin, M.D., Lota S. Zoth and Chad A. Johnson; and that the Lumos designees will be Emmett T. Cunningham, Jr., M.D., Richard J. Hawkins and Kevin Lalande.

Following the Merger, the management team of the combined company is expected to be composed of a combination of management teams from NewLink and Lumos. The following table lists the names and positions of the individuals who are expected to serve as executive officers and directors of the combined company upon the completion of the Merger:

Name	Age	Position(s)
Executive Officers		
Richard J. Hawkins[1]	70	Chief Executive Officer and Director
Carl W. Langren	64	Chief Financial Officer
Eugene P. Kennedy, M.D.	51	Chief Medical Officer
John McKew, Ph.D.	55	Chief Science Officer
Bradley J. Powers	41	General Counsel
Lori D. Lawley	36	VP, Finance and Controller
Directors		
Thomas A. Raffin, M.D.[2]	72	Director
Lota S. Zoth[2]	60	Director
Chad A. Johnson[2]	41	Director
Emmett T. Cunningham, Jr., M.D.[1]	58	Director
Kevin Lalande[1]	47	Director

(1) Lumos designee

(2) NewLink designee

Directors Designated by NewLink

Thomas A. Raffin, M.D., has served as a member of the NewLink Board since 1999 and has been NewLink Board's Lead Independent Director since October 2010. Dr. Raffin has spent 30 years on the faculty at Stanford University School of Medicine, where he is the Colleen and Robert Haas Professor Emeritus of

Medicine and Biomedical Ethics. Over the past two decades, Dr. Raffin has worked extensively in the healthcare and medical device business sectors and was an advisor to Cell Therapeutics Inc. from 1993 to 1997, Broncus Technologies from 1997 to 2004, iMedica from 1998 to 2002, and Inhale Technologies from 1998 to 2001. He co-founded Rigel Pharmaceuticals, a publicly traded company (Nasdaq: RIGL), in 1996. In 2001, he co-founded Telegraph Hill Partners, a San Francisco life sciences private equity firm as a General Partner. Dr. Raffin has been a director of the following Telegraph Hill Partners private portfolio companies: AngioScore, Inc., Confirma, Inc., Freedom Innovations, LDR Holding Corporation, PneumRx, Inc., Akoya BioSciences, Inc. and InvisALERT Solutions. Dr. Raffin received a B.A. from Stanford University and an M.D. from Stanford University School of Medicine and did his medical residency at the Peter Bent Brigham Hospital (now Brigham and Women's Hospital) in Boston, MA.

The NewLink Board believes that Dr. Raffin's extensive medical and business background and experience provides important experience in business operations and medical technology for him to serve as a member of the NewLink Board.

Chad A. Johnson, J.D., has served as a member of the NewLink Board since March 2018. Mr. Johnson is currently General Counsel at Stine Seed Company. From May 2015 to April 2017, Mr. Johnson was the Assistant Corporate Secretary and Senior Corporate Counsel for Renewable Energy Group, Inc., a supplier of advanced biofuels in North

America. In addition to his role as a corporate officer, Mr. Johnson was a senior in-house attorney for the company. From 2007 to April 2015, he spent eight years in roles of increasing responsibility at DuPont Pioneer, a subsidiary of DuPont and a global leading seed and agriculture biotechnology company. Mr. Johnson is admitted to practice law in the State of Iowa and before the United States Patent and Trademark Office. Mr. Johnson graduated from Iowa State University with a Master of Science in Crop Production and Physiology and received his J.D. from Drake University Law School.

The NewLink Board believes that Mr. Johnson's career at major biotechnology companies, service as a public company officer and experience overseeing various legal matters provides him with the background necessary for him to serve as a member of the NewLink Board.

Lota S. Zoth, CPA, has served as a member of the NewLink Board and Chair of the Audit Committee since November 2012. Ms. Zoth currently serves on the Board of Directors of Spark Therapeutics, Inc., (Nasdaq: ONCE) Zymeworks, Inc. and Inovio Pharmaceuticals, Inc. She also previously served on the Board of Directors for nonprofit Aeras from 2011 to 2018, Circassia Pharmaceuticals, PLC from 2015 to 2019, Hyperion Therapeutics, Inc. from 2008 to May 2015, Ikaria, Inc. from 2008 to 2014 and Orexigen Therapeutics, Inc. from 2012 to 2019. Prior to her board service, Ms. Zoth served as Chief Financial Officer of MedImmune, Inc. from 2004 through 2007, and as its Corporate Controller from 2002 to 2004. Prior to that, Ms. Zoth was a financial executive at several companies, including Sodexho Marriott Services, Inc., PSINet Inc., Marriott International, Inc. and PepsiCo, Inc. Ms. Zoth began her career as an auditor at Ernst & Young, LLP. Ms. Zoth received a BBA in accounting, summa cum laude, from Texas Tech University.

The NewLink Board believes that Ms. Zoth's experience with NewLink, as a director since 2012, brings continuity to the NewLink Board, and her extensive financial background and experience provides important experience in corporate finance, corporate management, and investor relations for her to serve as a member of the NewLink Board.

Directors Designated by Lumos

Richard J. Hawkins has served as President and Chief Executive Officer and as a member of the Lumos Board since January 2011. In addition, Mr. Hawkins currently serves on the board of directors of several life sciences companies, including Cytori Therapeutics, Inc. (Nasdaq: CYTX) and Savara Inc. (Nasdaq: SVRA), and previously served on the board of directors of SciClone Pharmaceuticals, Inc. until its acquisition in October 2017. From 2000 to 2010, Mr. Hawkins, founded and advised numerous pharmaceutical companies including Sensus, where he served as co-founder and Chairman until it was sold to Pfizer. From 1981 to 2000, Mr. Hawkins was founder, President and CEO of Pharmaco. The company later merged with PPD of Wilmington, NC to form PPD Pharmaco, one of the largest clinical contract research organizations in the world. Mr. Hawkins received his B.S. degree in Biology from Ohio University.

The NewLink Board believes that Mr. Hawkins's experience in the pharmaceutical and life sciences industries as well as his broad management experience qualify him to serve on the NewLink Board.

Emmett T. Cunningham, Jr., M.D., has served as a board observer of the Lumos Board since 2016 and as a member of the Lumos Board since 2019. In addition, Dr. Cunningham is a Senior Managing Director in the Blackstone Life Sciences group, having joined Blackstone as part of its acquisition of Clarus in December of 2018. Dr. Cunningham joined Clarus in 2006 as a principal. Dr. Cunningham has led investments in the medical technology, and biotechnology space including partnerships with pharmaceutical companies. Prior to joining Clarus, Dr. Cunningham was the Senior Vice President, Medical Strategy at Eyetech Pharmaceuticals, Inc. where he led the team that developed Macugen, a first-in-class product for the treatment of age-related macular degeneration. Prior to Eyetech, Dr. Cunningham was at Pfizer, Inc. (NYSE: PFE). Dr. Cunningham is an internationally recognized specialist in infectious and inflammatory eye disease with over 350 publications. In addition, Dr. Cunningham is a member of the boards of directors of Annexon Biosciences, Galera Therapeutics, Graybug Vision, and SFJ Pharmaceuticals Group, and serves on the Scientific Advisory Board of Aerie Pharmaceuticals (Nasdaq: AERI). Dr. Cunningham is the founder and chairman of the Ophthalmology Innovation Summit symposium held in conjunction with the annual meetings of the American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery. Dr. Cunningham received an M.D. and MPH in epidemiology and statistics from Johns Hopkins University and a Ph.D. in neuroscience from the University of California at San Diego for work done at The Salk Institute.

The NewLink Board believes that Dr. Cunningham's experience in the pharmaceutical and life sciences industries, as well as his training as a physician, qualify him to serve on the NewLink Board.

Kevin Lalande has served as a member of the Lumos Board since 2014. Mr. Lalande is also a Co-Founder and Managing Director of Santé Ventures, a healthcare and life science venture capital firm founded in 2006 which currently manages $380 million across three funds with 30 portfolio company investments. Mr. Lalande is also the Founder and Chief Investment Officer of Santé Capital, a systematic machine learning hedge fund that began trading capital in 2015 after three years of research and development. Mr. Lalande conceived the investment strategy, designed the original MindRank algorithms, and assembled a seasoned team to help drive this related line of business. Before Santé Ventures and Santé Capital, Mr. Lalande spent seven years as an investment professional with Austin Ventures, a prominent venture capital firm with $4.0 billion under management. Prior to Austin Ventures, he was a management consultant with McKinsey & Company. Before McKinsey, he founded, built and sold three internet-based companies in the 1990s. Mr. Lalande received a B.S. in Electrical & Computer Engineering with Honors in 1996 from Brigham Young University and an MBA with highest distinction from the Harvard Business School in 2001, where he was both a Baker Scholar and a Siebel Scholar.

The NewLink Board believes that Mr. Lalande's extensive experience as an investor and board member in pharmaceutical and life sciences companies and his knowledge gained from service on such boards qualify him to be a member of the NewLink Board.

Executive Officers

Carl W. Langren has served as our Chief Financial Officer since July 2018. Previously, he was our Vice President of Finance since November 2011 and has also been Chief Financial Officer of our subsidiary BioProtection Systems Corporation since February 2005. Prior to NewLink, Mr. Langren previously served as Chief Financial Officer for each of Housby Mixer Group from 1998 to 2002 and Equity Dynamics, Inc. from 1988 to 1989. He also served as a Principal in Capital Management Solutions, President of Iowa Machinery and Supply, Treasurer of DFM Corporation, and Tax Manager with McGladrey Pullen and Company. Mr. Langren received his B.A. degree from the University of Iowa.

Eugene P. Kennedy, M.D., FACS, has served as our Chief Medical Officer since November 2017, where he leads clinical development across all immuno-oncology product candidates as well as investigator initiated trials. From January 2014 to November 2017, Dr. Kennedy served as our Vice President for Clinical and Medical Affairs. Prior to joining NewLink, he was on faculty and clinical staff at Thomas Jefferson University in Philadelphia, Pennsylvania where he served as Associate Professor of Surgery and held leadership positions as Chief of the Section of Pancreaticobiliary Surgery and co-director of the Jefferson Pancreas, Biliary, and Related Cancers Center from January 2006 to December 2013. Previously, Dr. Kennedy held faculty positions at Johns Hopkins Hospital and the Louisiana State University School of Medicine. Dr. Kennedy obtained his undergraduate education at the University of Virginia and received his medical degree from the Medical College of Virginia. He completed a residency and fellowship in Surgery and Surgical Oncology as well as a research fellowship in tumor immunology at the Johns Hopkins Hospital.

John McKew, Ph.D., has served as the Chief Scientific Officer of Lumos since 2016. From 2014 until 2016, Dr. McKew was V.P. of research for aTyr Pharma where he led research aimed at understanding and harnessing the therapeutic potential of tRNA synthetases. From 2010 until 2014, Dr. McKew worked for the NIH, during which time he served as a branch chief at the National Human Genome Research Institute Home (the "NHGRI") from 2010 until 2013, and as the acting Scientific Director of the Division of Preclinical Innovation at the National Center for Advancing Translational Sciences ("NCATS") from 2013 until 2014. His responsibilities included developing both the Therapeutics for Rare and Neglected Disease ("TRND") and the Bridging Interventional Development Gaps ("BrIDGs") programs. The department he led also included NCATS's high throughput screening center and its Tox21 in vitro toxicology initiative. Before joining the NIH, Dr. McKew held a director level position at Wyeth Research in Cambridge, Massachusetts. Dr. McKew is also currently an Adjunct Associate Professor at the Boston University School of Medicine. Dr. McKew received a B.S. degree in chemistry and biochemistry from State University of New York at Stony Brook, a Ph.D. in organic chemistry from the University of California, Davis, and held post-doctoral research positions at the University of Geneva and Firmenich, SA.

Bradley J. Powers has served as our General Counsel since August 2015. Prior to joining NewLink, Mr. Powers served as the General Counsel of Kinze Manufacturing, an agricultural equipment manufacturer in North America, since March 2013. Mr. Powers received a B.S. degree in biology and a M.S. degree in bioinformatics and computational biology from Iowa State University and a J.D. from Drake University Law School.

Lori D. Lawley has served as NewLink's Vice President – Finance and Controller and the principal accounting officer since July 2018. Previously, Ms. Lawley served as NewLink's Manager of SEC Reporting and Accounting Policy from April 2015 until January 2017, Director of SEC and Financial Reporting from January 2017 to November 2017 and Corporate Controller from November 2017 until July 2018. Prior to joining NewLink, Ms. Lawley worked as an auditor at Ernst and Young LLP where she served in increasing capacities from 2007 through April 2015, including as Manager from October 2011 to September 2014, and Senior Manager from October 2014 until April 2015. Ms. Lawley is a licensed certified public accountant. Ms. Lawley received her Bachelor of Business Administration and Master's in Professional Accounting from the University of Texas.

Family Relationships

There are no family relationships among any of NewLink's directors and executive officers, and there are no family relationships among any of the combined company's proposed directors and executive officers.

Composition of the Board of Directors

The combined company's board of directors will consist of the six members identified above immediately after the Effective Time. Following the closing of the Merger, the combined company's board of directors will unanimously appoint a seventh member.

The combined company's board will be divided into three classes. Each class will consist, as nearly as possible, of one-third of the total number of directors, and each class will have a three-year term. Vacancies on the combined company's board of directors may be filled only by persons elected by a majority of the remaining directors. A director elected by the board of directors to fill a vacancy in a class, including vacancies created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until the director's successor is duly elected and qualified. Dr. Raffin is currently a Class II director with a term set to expire at the 2020 annual meeting of stockholders and Mr. Johnson and Ms. Zoth are each Class III directors with terms set to expire at the 2021 annual meeting of stockholders. The NewLink Board will determine the classes in which each member of the combined company's board of directors identified above shall serve, effective immediately after the Effective Time.

Committees of the Board of Directors

After completion of the Merger, the combined company's board of directors will have an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee, in each case established in accordance with applicable Nasdaq and SEC rules and regulations. Dr. Raffin and Ms. Zoth currently serve on our Audit Committee. Dr. Raffin, Ms. Zoth and Mr. Johnson currently serve on our Compensation Committee. Dr. Raffin and Mr. Johnson currently serve on our Nominating and Corporate Governance Committee. The NewLink Board will determine the committees in which each member shall serve, effective immediately after the Effective Time, in accordance with applicable Nasdaq and SEC rules and regulations.

Director Independence

The NewLink Board will undertake a review of the independence of the proposed directors of the combined company and consider whether any director has a material relationship with the combined company that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. We expect that all of the proposed directors, except Mr. Hawkins, due to his position as the chief executive officer of the combined company, will be deemed "independent" as that term is defined under the rules of Nasdaq rule 5605.

In making such determinations, the NewLink Board will consider the current and prior relationships that each non-employee director has with the combined company and all other facts and circumstances the NewLink Board deems relevant in determining their independence, including the beneficial ownership of capital stock by each non-employee director.

Combined Company Non-Employee Director Compensation Policy

The combined company expects to adopt a non-employee director compensation policy, pursuant to which non-employee directors will be eligible to receive compensation for service on the combined company's board of directors and committees of the board of directors.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

The unaudited pro forma condensed combined financial information does not give effect to the proposed reverse stock split described in Proposal 2 (the Reverse Stock Split Proposal) in this proxy statement.

On September 30, 2019, NewLink entered into the Merger Agreement with Lumos, with Lumos ultimately becoming a wholly owned subsidiary of NewLink and the surviving corporation following completion of the Merger in accordance with the Merger Agreement. The Merger is subject to the satisfaction of customary closing conditions, including approval by the stockholders of NewLink of the issuance of shares of NewLink common stock pursuant to the Merger Agreement, as well as the resulting "change of control" of NewLink under Nasdaq rules.

Immediately after the Merger, Lumos stockholders will own approximately 50% of the outstanding common stock of the combined company, with NewLink stockholders also owning approximately 50% of the outstanding common stock of the combined company.

The following unaudited pro forma condensed combined financial statements give effect to the Merger and were prepared in accordance with the regulations of the SEC. The unaudited pro forma condensed combined financial statements were prepared using the acquisition method of accounting under GAAP. For accounting purposes, Lumos is considered to be acquiring NewLink in the Merger. Lumos was determined to be the accounting acquirer based upon the terms of the Merger Agreement and other factors including: (i) Lumos stockholders will own approximately 50% of outstanding common stock of the combined company immediately following the closing of the Merger, (ii) the board of directors of the combined company will consist of three members designated by NewLink, three members designated by Lumos and the combined company's board of directors will unanimously appoint a seventh member and (iii) the combined company will be led by Lumos' current chief executive officer and chief scientific officer with other current members of senior management to include both Lumos and NewLink. For the purpose of these unaudited pro forma condensed combined financial statements, management of NewLink and Lumos have determined a preliminary estimated purchase price, calculated as described in Note 2 to these unaudited pro forma condensed combined financial statements. Further, the Merger is to be accounted for as an asset acquisition rather than a business combination because the assets acquired and liabilities assumed from NewLink do not meet the definition of a business as defined by ASC 805, *Business Combinations* as NewLink does not contain the processes in place to generate outputs. The net assets acquired and liabilities assumed in connection with the Merger are recorded at their estimated acquisition date fair values. A final determination of these estimated fair values will be based on the actual net assets of NewLink that exist as of the date of completion of the Merger.

The unaudited pro forma condensed combined balance sheet as of September 30, 2019 assumes that the Merger took place on September 30, 2019 and combines the historical balance sheets of NewLink and Lumos as of September 30, 2019. The unaudited pro forma condensed combined statements of operations for the nine months ended September 30, 2019 and for the year ended December 31, 2018 assume that the Merger took place as of January 1, 2018 and combine the historical results of NewLink and Lumos for the nine months ended September 30, 2019 and for the year ended December 31, 2018, respectively. The historical financial statements of NewLink and Lumos, which are provided (or incorporated by reference) elsewhere in this proxy statement, have been adjusted to give pro forma effect to events that are (i) directly attributable to the Merger, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results.

The unaudited pro forma condensed combined financial statements are based on the assumptions and adjustments that are described in the accompanying notes. The unaudited pro forma condensed combined financial statements and pro forma adjustments have been prepared based on preliminary estimates of fair value of assets acquired and liabilities assumed. Differences between these preliminary estimates and the final fair value of assets and liabilities acquired may occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial statements and the combined company's future results of operations and financial position. The actual amounts recorded as of the completion of the Merger may differ materially from the information presented in these unaudited pro forma condensed combined financial statements as a result of the amount of cash used by NewLink's operations between the signing of the Merger Agreement and the closing of the Merger; the timing of the closing of the Merger; and other changes in NewLink's assets and liabilities that occur prior to the Merger.

The unaudited pro forma condensed combined financial statements do not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the acquisition. The unaudited pro forma condensed combined financial statements have been prepared for illustrative purposes only and are not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had NewLink and Lumos been a combined company during the specified period. The unaudited pro forma condensed combined financial statements,

including the notes thereto, should be read in conjunction with the NewLink and Lumos historical audited financial statements for the year ended December 31, 2018 and the unaudited financial statements for the nine months ended September 30, 2019 included or incorporated by reference in this proxy statement.

UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET

As of September 30, 2019
(in thousands, except per share information)

	NewLink Historical	Lumos Historical	Pro Forma Adjustments	Notes	Pro Forma Combined
Current assets					
Cash and cash equivalents	$ 98,527	$ 7,665	$ —		$ 106,192
Prepaid expenses and other current assets	3,311	325	—		3,636
Income tax receivable					

76

—

—

76

Other receivables

740

—

—

740

Total current assets

102,654

7,990

—

110,644

Property and Equipment

10,472

235

(7,583
)
D

3,124

Less accumulated depreciation and amortization

(7,583
)

(146
)

7,583

D

(146
)
Property and Equipment, net

2,889

89

—

2,978

Right-of-use-asset

1,042

—

—

1,042

Deferred taxes - non-current

69

—

—

69

Economic interest in PRV

—

—

39,600

D

39,600

Other intangible assets

—

—

726

D

—

—

—

(726
)
G

—

Total assets
$
106,654

$
8,079

$
39,600

$
154,333

Current liabilities

Accounts payable
$
145

$
396

$
—

$
541

Accrued expenses

12,125

1,318

2,175

E

531

F

16,149

Current portion of lease liability

1,712

—

—

1,712

Current portion of notes payable and obligations under capital lease

58

—

—

58

Total current liabilities

14,040

1,714

2,706

18,460

Long-term liabilities

Royalty obligation payable to Iowa Economic Dev Authority

6,000

—

6,000

Lease liability

217

—

217

Total long-term liabilities

6,217

—

—

6,217

Total liabilities

20,257

1,714

2,706

24,677

Series B redeemable convertible preferred stock

—

41,117

(41,117
)
A

—

Series A redeemable convertible preferred stock

—

21,652

(21,652
)
A

—

	NewLink Historical	Lumos Historical	Pro Forma Adjustments	Notes	Pro Forma Combined
Shareholders' equity					
Common stock	373	1	267	A	
			(1)	B	

106

B

746

Additional paid in capital

413,205

144

62,502

A

(105
)
B

(327,905
)
C

40,326

D

(1,451
)
J

186,716

Treasury stock

(1,451
)

—

1,451

J

—

Accumulated deficit

(325,730
)

(56,549
)

327,905

C

(2,175
)
E

(531
)
F

(726
)
G

**(57,806
)**

Total shareholders’ equity

86,397

**(56,404
)**

99,663

129,656

Total liabilities and shareholders’ equity

106,654

(54,690

)					
102,369					
154,333					
Total liabilities, redeemable convertible preferred stock and stockholders' equity					
$					
106,654					
$					
8,079					
$					
39,600					
$					
154,333					

See accompanying notes to the Unaudited Pro Forma Condensed Combined Financial Information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS

Nine Months Ended September 30, 2019
(in thousands, except per share information)

	NewLink Historical	Lumos Historical	Pro Forma Adjustments	Notes	Pro Forma Combined
Operating revenues					
Grant revenue	$ —	$ —	$ —		$ —
Licensing revenue	503	—	—		503
Total revenue	**503**	—	—		**503**

503

Operating expenses

Research and development expenses

17,465

4,538

—

22,002

General and administrative expenses

19,484

2,893

(2,512
)
H

19,865

Total operating expenses

36,948

7,431

(2,512
)

41,867

Loss from operations

(36,445
)

(7,431
)

2,512

(41,364
)

Other (income) expense

Miscellaneous income

(38
)

—

—

(38
)
Interest income

1,815

88

—

1,903

Interest expense

(50
)

—

—

(50
)

Total other income, net

1,727

88

—

1,815

Net loss before taxes

**(34,718
)**

**(7,343
)**

2,512

(39,549
)

Income tax benefit

—

—

—

—

Net loss	**$ (34,718)**	**$ (7,343)**	**$ 2,512**
	$ (39,549)		

Basic and diluted loss per share	$ (0.93)	$ —	$ (0.52)
Basic and diluted average shares outstanding	37,286,930	38,896,864	I 76,183,794

See accompanying notes to the Unaudited Pro Forma Condensed Combined Financial Information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS

Year Ended December 31, 2018
(in thousands, except per share information)

	NewLink Historical	Lumos Historical	Pro Forma Adjustments	Notes	Pro Forma Combined
Operating revenues					
Grant revenue	$ 11,268	$ —	$ —		$ 11,268
Licensing revenue	1,206	—	—		1,206
Total revenue	**12,474**				

—

—

12,474

Operating expenses

Research and development expenses

45,694

8,753

—

54,447

General and administrative expenses

29,218

2,533

—

31,751			
Total operating expenses			
74,912			
11,286			
—			
86,198			
Loss from operations			
(62,438)			
(11,286)			
—			
(73,724)			
Other (income) expense			
Miscellaneous income			
(102)			
—			

—

(102
)
Interest income

2,029

124

—

2,153

Interest expense

(52
)

—

—

(52
)
Total other (income) expense

1,875

124

—

1,999

Net loss before taxes

**(60,563
)**

**(11,162
)**

—

**(71,725
)**
Income tax benefit

6,968

—			
—			
6,968			
Net loss			
$	**$**	**$**	**$**
(53,595)	**(11,162)**	—	**(64,757)**
Basic and diluted loss per share			
$ (1.44)		$ —	$ (0.85)
Basic and diluted average shares outstanding			
37,191,262			39,214,519

76,405,781

See accompanying notes to the Unaudited Pro Forma Combined Financial Information.

NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

Note 1 – Basis of Presentation

The unaudited pro forma condensed combined financial statements are based on Lumos' and NewLink's historical consolidated financial statements as adjusted to give effect to the reverse merger. The unaudited pro forma condensed combined statements of operations for the nine months ended September 30, 2019 and the year ended December 31, 2018 give effect to the reverse merger as if it had occurred on January 1, 2018. The unaudited pro forma condensed combined balance sheet as of September 30, 2019 gives effect to the reverse merger as if it had occurred on September 30, 2019. The historical financial information has been adjusted in the unaudited pro forma condensed combined financial statements to give effect to pro forma events that are (i) directly attributable to the acquisition, (ii) factually supportable, and (iii) with respect to the statements of operation, expected to have a continuing impact on the combined company's results. The Merger was accounted for as an asset acquisition rather than a business combination because the assets acquired and liabilities assumed by Lumos do not meet the definition of a business as defined by ASU 2017-01 as NewLink does not contain the processes in place to generate outputs. The net assets to be acquired in connection with the Merger were recorded at their estimated acquisition date fair values as of September 30, 2019, the date the Merger Agreement was executed.

The pro forma adjustments described below were based on management's assumptions and estimates, including assumptions relating to the consideration paid and the allocation thereof to the assets acquired and liabilities assumed from NewLink based on preliminary estimates of fair value. The final purchase consideration and the allocation of the purchase consideration may differ from that reflected in the unaudited pro forma condensed combined financial information after final valuation procedures are performed and amounts are finalized following the completion of the reverse merger.

The pro forma condensed combined financial statements do not necessarily reflect what the combined company's financial condition or results of operations would have been had the reverse merger occurred on the dates indicated. They also may not be useful in predicting the future financial condition and results of operations of the combined company. The actual financial position and results of operations may differ significantly from the pro forma amounts reflected herein due to a variety of factors.

The unaudited pro forma condensed combined financial information does not reflect any integration activities or cost savings from operating efficiencies, synergies, asset dispositions, or other restructurings that could result from the reverse merger.

Note 2 – Estimated Consideration and Preliminary Purchase Price Allocation

The estimated fair value of the net assets of NewLink on a pro forma basis on September 30, 2019, after giving effect of accruals of costs expected to be incurred in connection with the Merger was $124.5 million. As NewLink's assets were predominately comprised of cash offset by current liabilities, the pro forma carrying value of NewLink's net assets, which have been adjusted by the fair value of acquired intangible assets not previously reflected on NewLink's balance sheet, is considered to be the best indicator of the fair value and, therefore, the preliminary estimated purchase price as of September 30, 2019. The estimated preliminary purchase price at the Merger closing date will change due to the amount of cash used by NewLink's operations after September 30, 2019 to the closing of the Merger and other changes in the NewLink assets and liabilities that occur through the completion of the Merger. The preliminary purchase price assigned a value to the assets and liabilities acquired based on the accumulated cost of the acquisition and allocated based on the acquired assets and liabilities relative fair value. Given the cost of the acquisition was computed based on the fair value of the net assets acquired, the relative fair values assigned equate to the computed fair values of the acquired assets and liabilities.

The preliminary acquired net assets of NewLink based on their pro forma estimated fair values as of September 30, 2019 are as follows (in thousands):

Assets acquired	
Cash & cash equivalents	$ 98,527
Prepaid and other current assets	4,127
Property and equipment	2,889
Economic interest in PRV	39,600
Other intangible assets	726
Other non-current assets	1,111
Total assets acquired	146,980
Liabilities assumed	
Accounts payable	145
Accrued expenses and other current liabilities	13,895
Royalty obligation payable to Iowa Economic Development Authority	6,000
Other long-term liabilities	217
Total liabilities assumed	20,257
Less: Transaction costs	2,175
Total net assets acquired less transaction costs	$

The allocation of the estimated purchase price is preliminary because the proposed Merger has not yet been completed. The purchase price allocation will remain preliminary until Lumos determines the fair values of assets acquired and liabilities assumed. The final determination of the purchase price allocation is anticipated to be completed as soon as practicable after completion of the Merger and will be based on the fair values of the assets acquired and liabilities assumed as of the Merger closing date. The final amounts allocated to assets acquired and liabilities assumed could differ significantly from the amounts presented in the unaudited pro forma condensed combined financial statements.

Note 3 – Unaudited Pro Forma Adjustments

A. To reflect the conversion of all Lumos preferred stock to NewLink common stock in connection with the Merger.

B. To reflect the conversion of Lumos common stock to NewLink common stock in connection with the Merger.

C. To reflect the elimination of NewLink's historical accumulated deficit.

D. To reflect the fair values of the NewLink assets acquired and liabilities by Lumos. The fair value of the Economic interest in PRV relates to the fair value expected to be received upon the issuance and monetization of the PRV to NewLink's licensee, Merck, when the BLA for the licensed Ebola vaccine is approved by the FDA. Upon the written request of NewLink, Merck will transfer and assign all ownership interest in the PRV to NewLink. Upon transfer of such ownership interest in the PRV to NewLink, NewLink intends to sell the PRV in the open market. NewLink does not intend to use the PRV for any purpose other than sale in the open market for cash consideration. Management computed the fair value by assigning a probability of success of 90.35% based on management's best estimate of the likelihood of successful approval of the BLA to an estimated transaction price of $80.6 million, less expected taxes and the 40 percent ownership by Merck. Management used the Tuft's Clinical Phase Transition Success Rate for BLA to Approval of 85.3%, which is the estimate for all diseases and all modalities and adjusted this estimate to 90.35%. Management increased the percentage to account for the current Ebola healthcare crisis and the fact that the vaccine has been in use by healthcare authorities for some time now and it is the first preventative against Ebola available. NewLink used an estimated transaction price of $80.6 million based on the low end of the range using the first and third quartile transaction values of six publicly disclosed transactions of $80.6 million to $105.0 million, respectively, since 2018. This reflects the most current observable inputs and trends in the market of PRVs and accounts for the decline in the transaction values since the peak sale of $350.0 million in 2015.

Subsequent to the initial valuation, the FDA approved its application for ERVEBO® (Ebola Zaire Vaccine, Live) for the prevention of disease caused by Zaire ebola virus in individuals 18 years of age and older on December 20, 2019. The fair values of the NewLink assets did not attribute any value to future royalties that NewLink might be entitled to receive under the Merck Agreement because management did not believe that any such royalties would be paid in the foreseeable future, if ever.

E. To record NewLink's estimated transaction costs, which include legal and advisory fees other transaction related fees that were not incurred as of September 30, 2019.

F. To record Lumos' estimated transaction costs, which include legal and advisory fees other transaction related fees that were not incurred as of September 30, 2019.

G. To record the research and development costs for the in-process research and development acquired from NewLink that has no future alternative use.

H. To reflect elimination of transaction costs, which include legal and advisory fees and other transaction related fees.

I. Adjustment reflects the additional NewLink common stock anticipated to be issued as part of the Merger at the exchange ratios defined within the agreement adjusted for the Lumos weighted average number of shares of common stock outstanding during the period adjusted based on the anticipated exchange ratio for NewLink common stock. As the combined company is in a net loss position, any adjustment for potentially dilutive shares would be anti-dilutive, and as such basic and diluted loss per share are the same.

The tables below reflect the pro forma adjustments (in thousands, except share and per share data):

	Pro Forma Nine Months Ended September 30, 2019	**Pro Forma Year Ended December 31, 2018**
Pro forma net loss	$ (39,549)	$ (64,757)
Basic and diluted net loss per share	(0.52)	(0.85)
Basic and diluted weighted average shares outstanding	76,183,794	76,405,781

The calculation of pro forma basic and diluted weighted average shares is as follows:

	Pro Forma Nine Months Ended September 30, 2019	**Pro Forma Year Ended December 31, 2018**
Basic and diluted weighted average shares:		
NewLink historical weighted average shares outstanding	37,286,930	37,191,262
Lumos historical weighted average number of shares outstanding, converted using defined exchange ratios	38,896,864	39,214,519
Pro forma basic and diluted weighted average shares outstanding	76,183,794	76,405,781

J. To reflect the elimination of 112,768 shares of NewLink treasury stock and 1,350,000 shares of Lumos treasury stock that will be cancelled in connection with the merger.

DESCRIPTION OF NEWLINK'S COMMON STOCK

General

Under NewLink's Charter, NewLink is authorized to issue up to 75,000,000 shares of common stock, par value $0.01 per share, and 5,000,000 shares of NewLink's preferred stock, par value $0.01 per share. The NewLink Board may establish the rights and preferences of the preferred stock from time to time. As of December 31, 2019, NewLink had outstanding 37,325,091 shares of common stock and no shares of preferred stock outstanding or designated.

NewLink's common stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors, other than any amendment to the Charter that relates solely to the terms of one or more outstanding series of preferred stock, except as otherwise required by law. Our Charter and our Bylaws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of NewLink's common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to preferences that may apply to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any outstanding preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Preferred Stock

Pursuant to our Charter, the NewLink Board has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of NewLink's preferred stock in one or more series and to fix the number, rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control or other corporate action, or make the removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of the common stock.

The NewLink Board will fix the designations, voting powers, preferences and rights of each series, as well as the qualifications, limitations or restrictions thereof, of the preferred stock of each series that we offer under this prospectus and applicable prospectus supplements in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of that series of preferred stock. This description will include:

- the title and stated value;
- the number of shares we are offering;

- the liquidation preference per share;
- the purchase price per share;
- the dividend rate per share, dividend period and payment dates and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- our right, if any, to defer payment of dividends and the maximum length of any such deferral period;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock or other securities of ours, including depositary shares and warrants, and, if applicable, the conversion period, the conversion price, or how it will be calculated, and under what circumstances it may be adjusted;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange period, the exchange price, or how it will be calculated, and under what circumstances it may be adjusted;
- voting rights, if any, of the preferred stock;
- preemption rights, if any;
- restrictions on transfer, sale or other assignment, if any;
- whether interests in the preferred stock will be represented by depositary shares;
- a discussion of any material or special U.S. federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on issuances of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock being issued as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
- any other specific terms, rights, preferences, privileges, qualifications or restrictions of the preferred stock.

The DGCL, which is the law of the state of our incorporation, provides that the holders of preferred stock will have the right to vote separately as a class (or, in some cases, as a series) on an amendment to our Charter if the amendment would change the par value, the powers, preferences or special rights of the class or series so as to adversely affect the class or series, as the case may be, or, unless the Charter provided otherwise, the number of authorized shares of the class. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Stock Options and Restricted Stock Units

As of December 31, 2019, there were 12,400,653 shares of NewLink's common stock authorized under NewLink's equity incentive plan, of which 3,385,524 shares were reserved for issuance upon exercise of outstanding options, 1,891 shares were reserved for issuance upon the vesting of outstanding RSUs, and 7,504,568 shares of NewLink's common stock remained available for issuance.

As of December 31, 2019, there were 23,656 shares of NewLink's common stock reserved for issuance under NewLink's employee stock purchase plan, and 268,902 shares remained available for issuance under our non-employee directors' stock award plan.

Transfer Agent

The transfer agent and registrar for our common stock is Computershare Shareowners Services, LLC.

Listing

Our common stock is listed on Nasdaq under the symbol "NLNK." NewLink has filed an initial listing application with Nasdaq pursuant to Nasdaq's rules for companies conducting a business combination that results in a change of control. After completion of the Merger, NewLink will be renamed "Lumos Pharma, Inc." and expects to trade on Nasdaq under the symbol "LUMO." On November 19, 2019, the last trading day before the date of this proxy statement, the closing sale price of NewLink common stock was $1.60 per share.

Anti-Takeover Effects of Provisions of NewLink Charter Documents

Among other things, our Charter and our Bylaws provide for the following:

Our board of directors may issue up to 5,000,000 shares of NewLink's preferred stock, with such rights, preferences and privileges as the board of directors may designate.

The personal liability for monetary damages of our directors to us and to our stockholders is limited to the fullest extent permitted by applicable law, including, without limitation, the DGCL. This provision may reduce the likelihood of derivative litigation against directors and may discourage or deter stockholders or management from bringing a lawsuit against directors for breach of their fiduciary duty.

Special meetings of stockholders may only be called by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors, the chairman of the board of directors, or the chief executive officer. In addition, our Bylaws establish procedures, including requirements for advance written notice and the form and content for stockholder notices, with regard to the nomination of candidates for election as directors and stockholder proposals. These provisions may delay or preclude stockholders from bringing matters before a meeting of stockholders or from making nominations for directors at a meeting of stockholders, which could delay or deter takeover attempts or changes in management.

The NewLink Board is divided into three classes of directors, with each class serving staggered three-year terms. As a result, approximately one-third of the board of directors will be elected each year. The classified board provision could have the effect of discouraging a third party from making a tender offer or attempting to obtain control of us. In addition, the classified board provision could delay stockholders who do not agree with the policies of the board of directors from removing a majority of the board of directors for two years.

Our Charter does not provide for cumulative voting for our directors. The absence of cumulative voting may make it more difficult for stockholders owning less than a majority of our stock to elect any directors to our board of directors. In addition, directors may be removed only for cause, and removal requires the affirmative vote of the holders of 66 2/3% of our voting stock.

Subject to the rights of the holders of any outstanding series of our preferred stock, all vacancies, including newly created directorships, may, except as otherwise required by law, be filled only by the affirmative vote of a majority of our directors then in office, even if less than a quorum, unless the board of directors determines by resolution that any such vacancies will be filled by the stockholders. In addition, the authorized number of directors may be changed only by resolution of our board of directors.

Stockholders are permitted to amend our Bylaws only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Anti-Takeover Effects of Delaware Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the entity or person’s affiliates and associates, beneficially owns, or is an affiliate or associate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

PRINCIPAL STOCKHOLDERS OF NEWLINK

The following table sets forth certain information available to NewLink with respect to the beneficial ownership of NewLink capital stock as of December 31, 2019, for:

- each of NewLink's named executive officers then in office;
- each of NewLink's directors;
- all of NewLink's current directors and executive officers as a group; and
- each person known by NewLink to be the beneficial owner of more than 5% of the outstanding shares of NewLink common stock.

The number of shares beneficially owned by each entity, person, director or executive officer is determined under the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which the individual has the sole or shared voting power or investment power and also any shares that the individual has the right to acquire within 60 days of December 31, 2019, through the exercise of any stock option or other right. Unless otherwise indicated, each person has sole investment and voting power, or shares such powers with his or her spouse, with respect to the shares set forth in the following table. NewLink has based its calculation of percentage ownership of NewLink's common stock prior to the Merger on approximately 37.3 million shares of NewLink common stock outstanding on December 31, 2019.

Name and Address of Beneficial Owner[1]	Shares Beneficially Owned Prior to the Merger	
	Shares (#)	Percent (%)
Named Executive Officers and Directors		
Chad A. Johnson	—	—
Thomas A. Raffin, M.D.	64,621	*
Mathew L. Sherman, M.D.	—	—
Ernest J. Talarico, III[2]	38,065	*
Lota S. Zoth	7,906	*

Eugene P. Kennedy, M.D.(3)

35,294

*

Carl W. Langren(4)

91,313

*

Bradley J. Powers(5)

28,669

*

All current executive officers and directors as a group (9 persons)(6)

284,054

*

5% and Greater Stockholders

Stine Seed Farm, Inc.(7)

7,857,732

21.1
%

Renaissance Technologies LLC(8)

2,061,013

5.5
%

BlackRock Inc.(9)

1,871,127

5.0
%

---

* Indicates beneficial ownership of less than 1% of the outstanding shares of NewLink common stock.

(1) Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o NewLink Genetics Corporation, 2503 South Loop Drive, Suite 5100, Ames, IA 50010.

(2) Consists of 32,223 shares of common stock held by Mr. Talarico, 977 shares of common stock held by the Ernest J. Talarico III Roth IRA, 1,737 shares of common stock held by the Kelli A. Talarico Roth IRA, 1,564 shares of common stock held by the Ernest Joseph Talarico IV Irrevocable Investment Trust UAD 12/3/2014 and 1,564 shares of common stock held by the Eva Marie Talarico Irrevocable Investment Trust UAD 12/3/2014. Mr. Talarico's spouse is the trustee of each trust.

(3) Includes 21,197 shares Dr. Kennedy has the right to acquire through the exercise of stock options within 60 days of December 31, 2019 and 1,105 restricted stock units that vested on January 4, 2020.

(4) Consists of 21,197 shares Mr. Langren has the right to acquire through the exercise of stock options within 60 days of December 31, 2019, 786 restricted stock units that vested on January 4, 2020, 19,639 shares of common stock held by Mr. Langren and 49,691 shares of common stock held by the Susan A. Langren 2014 DGT Trust, of which Mr. Langren's spouse is the grantor.

(5) Consists of 27,916 shares Mr. Powers has the right to acquire through the exercise of stock options within 60 days of December 31, 2019, 503 shares of common stock held by Mr. Powers and 250 shares of common stock held by Mr. Power's spouse.

(6) Includes 85,414 shares issuable upon exercise of stock options exercisable within 60 days of December 31, 2019, 1,891 restricted stock units that vested on January 4, 2020, and 196,749

shares of common stock held by our current directors and executive officers, including Chad A. Johnson, Thomas A. Raffin, M.D., Matthew L. Sherman, Ernest J. Talarico, III, Lota S. Zoth, Eugene P. Kennedy, M.D., Lori D. Lawley, Carl W. Langren, and Bradley J. Powers.

(7) Address: 22555 Laredo Trail, Adel, Iowa 50003, Based solely upon a Schedule 13D filed with the SEC on October 6, 2017. Harry H. Stine, the CEO and President of Stine Seed Farm, Inc., may be deemed to beneficially own such shares.

(8) Address: 800 Third Avenue, New York, New York 10022. Based solely upon a Schedule 13G filed with the SEC on February 12, 2019 reflecting the beneficial ownership by Renaissance Technologies LLC as of December 10, 2018.

(9) Address: 55 East 52nd Street, New York, New York 10055. Based solely upon a Schedule 13G filed with the SEC on February 11, 2019 reflecting the beneficial ownership by BlackRock Inc. as of January 31, 2019.

PRINCIPAL STOCKHOLDERS OF LUMOS

The following table sets forth certain information with respect to the beneficial ownership of Lumos common stock prior to the Merger on an as-converted to common stock basis to reflect the beneficial ownership of shares of Lumos common stock based on shares outstanding as of December 31, 2019 for:

- each person, or group of affiliated persons, who are known by Lumos to beneficially own more than 5% of the outstanding shares of Lumos common stock;
- each of Lumos' directors;
- each of Lumos' named executive officers; and
- all of the current directors and executive officers of Lumos as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined under the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which the individual has the sole or shared voting power or investment power and any shares that the individual has the right to acquire within 60 days of December 31, 2019, through the exercise of any stock option or other right. Unless otherwise indicated, each person has sole investment and voting power, or shares such powers with his or her spouse, with respect to the shares set forth in the following table.

The percentage beneficial ownership prior to the Merger is based on 30,174,234 shares of Lumos common stock outstanding as of December 31, 2019, assuming the conversion of all outstanding shares of Lumos Series A preferred stock and Series B preferred stock, on a one-for-one basis into shares of Lumos common stock.

	Shares Beneficially Owned Prior to the Merger	
Name and Address of Beneficial Owner[1]	**Shares (#)**	**Percent (%)**
Named Executive Officers and Directors		
Cameron Wheeler	—	—
Carole Nuechterlein	—	—
Ed Mathers	—	—
Kevin Lalande[2]	4,312,136	14.3 %
Jon Saxe	2,150,000	

7.1
%
Emmett T. Cunningham Jr., M.D.(3)

—

—

Robert Heft(4)

125,647

*
Richard J. Hawkins(5)

5,543,750

18.3
%
John C. McKew, Ph.D.(6)

701,062

2.3
%
All current executive officers and directors as a group (9 persons)

12,832,595

41.3
%
5% and Greater Stockholders

Entities affiliated with New Enterprise Associates, Inc.(7)

5,275,097

17.5
%
Deerfield Private Design Fund III, L.P.(8)

4,690,019

15.5
%
Sante Health Ventures II, L.P.(9)

4,312,136

14.3
%
Clarus Lifesciences III, L.P.(10)

2,345,009

7.8
%
The Wellcome Trust Limited as trustee of the Wellcome Trust(11)

1,826,823

6.1
%

---

* Indicates beneficial ownership of less than 1% of the total outstanding shares of Lumos common stock.

(1) Unless otherwise indicated, the address of such individual is Lumos Pharma, Inc., 4200 Marathon Boulevard, Suite 200, Austin, Texas 78756.

(2) Consists of the shares held by Sante Health Ventures II, L.P. described in footnote (9) below. Mr. Lalande may be deemed to beneficially own such shares.

(3) Dr. Cunningham is a Senior Managing Director of an entity affiliated with Clarus Lifesciences III, L.P. Dr. Cunningham is not deemed to have any beneficial ownership in the shares held by Clarus Lifesciences III, L.P. described in footnote (10) below.

(4) Consists of 125,647 shares of Lumos common stock issuable pursuant to stock options.

(5) Consists of (i) 5,500,000 shares of Lumos common stock and (ii) 37,500 shares of Lumos common stock issuable pursuant to stock options and does not include an additional 62,500 shares of Lumos common stock issuable pursuant to stock options that become exercisable pursuant to acceleration of vesting upon a change of control at the consummation of the Merger.

(6) Consists of 671,994 shares of Lumos common stock issuable pursuant to stock options and does not include an additional 66,893 shares of Lumos common stock issuable pursuant to stock options which become exercisable pursuant acceleration of vesting upon change of control at the consummation of the Merger.

(7) Consists of (i) 30,143 shares of Series A preferred stock held by NEA Ventures 2013, L.P. ("Ven 2013") and (ii) 4,658,702 shares of Series A preferred stock and 586,252 shares of Series B preferred stock, in each case held by held by New Enterprise Associates 14, L.P. ("NEA 14") (collectively, the "NEA Shares"). The shares held by Ven 2013 are held indirectly by Karen P. Welsh, the general partner of Ven 2013. The shares held by NEA 14 are held indirectly by NEA Partners 14, L.P. ("NEA Partners 14"), the general partner of NEA 14, NEA 14 GP LTD ("NEA 14 LTD"), the general partner of NEA Partners 14, and the individual directors of NEA 14 LTD. The directors of NEA 14 LTD are Peter J. Barris, Forest Baskett, Anthony A. Florence, Patrick J. Kerins, David M. Mott, Scott D. Sandell, and Peter W. Sonsini. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their pecuniary interest therein. The address for each of these entities is c/o New Enterprise Associates, Inc., 1954 Greenspring Drive, Suite 600, Timonium, Maryland 21093.

(8) Consists of 4,690,019 shares of Lumos Series B preferred stock. Deerfield Mgmt III, L.P. is the general partner of, and Deerfield Management Company, L.P. is the investment advisor to, Deerfield Private Design Fund III, L.P. Mr. James E. Flynn is the sole member of the general partner of each of Deerfield Mgmt III, L.P. and Deerfield Management Company, L.P. The address for each of these entities and Mr. Flynn is 780 Third Avenue, 37th Floor, New York, NY 10017.

(9) Consists of 4,019,010 shares of Lumos Series A preferred stock and 293,126 shares of Lumos Series B preferred stock. Mr. Lalande, Joe Cunningham, M.D. and Douglas D. French, are managing directors (the "SHV Directors") of SHV Management Services II, LLC ("SHV Management"). SHV Management is the general partner of SHV Management Services II, LP, which is the general partner of Santé Health Ventures II, L.P. Each of the SHV Directors, SHV Management, and SHV Management Services II, LP disclaims beneficial ownership of these securities except to the extent of its or his pecuniary interest therein. The address for these entities and individuals is 500 W 5th Street, Suite 1215, Austin, TX 78701.

(10) Consists of 2,345,009 shares of Lumos Series B preferred stock held by Clarus Lifesciences III, L.P. ("Clarus"). Clarus Ventures III GP, L.P. is the sole general partner of Clarus. Blackstone Clarus III L.L.C. is the sole general partner of Clarus Ventures III GP, L.P. The sole member of Blackstone Clarus III L.L.C. is Blackstone Holdings II L.P. The sole general partner of Blackstone Holdings II L.P. is Blackstone Holdings I/II GP L.L.C. The sole member of Blackstone Holdings I/II GP L.L.C. is The Blackstone Group Inc. The sole holder of the Class C common stock of The Blackstone Group Inc. is Blackstone Group Management L.L.C. Blackstone Group Management L.L.C. is wholly-owned by The Blackstone Group Inc.'s senior managing directors and controlled by its founder, Stephen A. Schwarzman Each of such entities and Mr. Schwarzman may be deemed to beneficially own the shares beneficially owned by Clarus, but each (other than Clarus) disclaims beneficial ownership of such shares. The address for each of Clarus and Clarus Ventures III GP, L.P. is c/o Clarus Ventures LLC, 101 Main Street, Suite 1210, Cambridge, MA 02142. The address for each of the other Blackstone entities and Mr. Schwarzman is c/o The Blackstone Group Inc., 345 Park Avenue, New York, NY 10154.

(11) Consists of 1,826,823 shares of Lumos Series A preferred stock. The Wellcome Trust Limited, which is the trustee of the Wellcome Trust, is governed by its Board of Governors, which is comprised of Eliza Manningham Buller, Michael Ferguson, Tobias Bonhoeffer, William Burns, Amelia Fawcett, Richard Gillingwater, Bryan Grenfell, Fiona Powrie and Cilla Snowball. The principal address of The Wellcome Trust Limited as trustee of the Wellcome Trust is 215 Euston Road, London NW1 2BE, England.

PRINCIPAL STOCKHOLDERS OF THE COMBINED COMPANY

The following table sets forth certain information with respect to the beneficial ownership of the combined company's capital stock after the Merger, assuming the closing of the Merger occurred on December 31, 2019, for:

- each executive officer and director of the combined company;
- all of the combined company directors and executive officers as a group; and
- each person, or affiliated persons, expected by NewLink and Lumos to become a beneficial owner of more than 5% of the outstanding shares of the combined company.

The number of shares beneficially owned by each entity, person, director or executive officer is determined under the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which the individual has the sole or shared voting power or investment power and also any shares that the individual has the right to acquire within 60 days of December 31, 2019, through the exercise of any stock option or other right. Unless otherwise indicated, NewLink and Lumos believe, based on the information furnished to each company, that each of the persons named in the table below has sole investment and voting power, or shares such powers with his or her spouse, with respect to the shares set forth in the following table.

The percentage beneficial ownership following the consummation of the Merger assumes the Merger had closed on December 31, 2019 and gives effect to (i) the automatic exchange of 9,003,433 shares of Lumos common stock into an aggregate of 10,603,543 shares of NewLink common stock, (ii) the automatic exchange of 11,204,513 shares of Lumos' outstanding Series A preferred stock into an aggregate of 8,811,407 shares of NewLink common stock pursuant to the Series A Exchange Ratio, and (iii) the automatic exchange of 9,966,288 shares of Lumos' outstanding Series B preferred stock into an aggregate of 17,910,139 shares of NewLink common stock pursuant to the Series B Exchange Ratio, in each case using a calculation of applicable exchange ratios based on approximately 37.3 million outstanding shares of NewLink common stock as of December 31, 2019 and in accordance with the terms of the Merger Agreement. Applicable percentage ownership below is based on 74,650,182 shares of combined company common stock as of December 31, 2019.

	Shares Beneficially Owned Post Merger	
Name and Address of Beneficial Owner[1]	**Shares (#)**	**Percent (%)**
Executive Officers and Directors		
Chad A. Johnson[2]	37,313	*
Thomas A. Raffin, M.D.[3]	136,610	*
Lota S. Zoth[4]	58,980	*
Emmett T. Cunningham, Jr., M.D.[5]	—	—
Kevin Lalande[6]	3,687,381	4.9%
Richard J. Hawkins[7]	6,595,243	

8.8%
Eugene P. Kennedy, M.D.(8)

110,880

*
John McKew, Ph.D.(9)

862,544

1.1%
Carl W. Langren(10)

156,359

*
Bradley J. Powers(11)

53,635

*
Lori D. Lawley(12)

32,327

*
All current executive officers and directors as a group (11 persons)(13)

11,731,271

15.4%
5% and Greater Stockholders

Deerfield Private Design Fund III, L.P.(14)

8,428,303

11.3%
Stine Seed Farm, Inc.(15)

7,857,732

10.5%
Entities affiliated with New Enterprise Associates, Inc.(16)

4,740,918

6.4%
Clarus Lifesciences III, L.P.(17)

4,214,150

5.6%

---

* Indicates beneficial ownership of less than 1% of the outstanding shares of the combined company's common stock.

(1) Unless otherwise indicated, the address of such individual is Lumos Pharma, Inc., 4200 Marathon Boulevard, Suite 200, Austin, Texas 78756.

(2) Consists of 37,313 shares Mr. Johnson has the right to acquire through the exercise of stock options within 60 days of December 31, 2019.

(3) Includes 71,989 shares Dr. Raffin has the right to acquire through the exercise of stock options within 60 days of December 31, 2019.

(4) Includes 48,974 shares Ms. Zoth has the right to acquire through the exercise of stock options within 60 days of December 31, 2019 and 2,100 fully vested restricted stock units that were issued on January 2, 2020.

(5) Dr. Cunningham is a Senior Managing Director of an entity affiliated with Clarus Lifesciences III, L.P. Dr. Cunningham is not deemed to have any beneficial ownership in the shares held by Clarus Lifesciences III, L.P. described in footnote (17) below.

(6) Consists of the shares held by Sante Health Ventures II, L.P. Mr. Lalande may be deemed to beneficially own such shares. Mr. Lalande, Joe Cunningham, M.D. and Douglas D. French, are managing directors (the "SHV Directors") of SHV Management Services, LLC ("SHV Management"). SHV Management is the general partner of SHV Management Services, LP, which is the general partner of Santé Health Ventures II, L.P. Each of the SHV Directors, SHV Management, and SHV Management Services, LP disclaims beneficial ownership of these securities except to the extent of its or his pecuniary interest therein. The address for this entity is 401 Congress Avenue, Suite 2950, Austin, TX 78701.

(7) Includes 117,771 shares Mr. Hawkins has the right to acquire through the exercise of stock options within 60 days of December 31, 2019.

(8) Includes 96,783 shares Dr. Kennedy has the right to acquire through the exercise of stock options within 60 days of December 31, 2019 and 1,105 RSUs that vested on January 4, 2020.

(9) Consists of 862,544 shares Dr. McKew has the right to acquire through the exercise of stock options within 60 days of December 31, 2019.

(10) Consists of 86,243 shares Mr. Langren has the right to acquire through the exercise of stock options within 60 days of December 31, 2019, 786 RSUs that vested on January 4, 2020, 19,639 shares of common stock held by Mr. Langren and 49,691 shares of common stock held by the Susan A. Langren 2014 DGT Trust, of which Mr. Langren's spouse is the grantor.

(11) Consists of 52,882 shares Mr. Powers has the right to acquire through the exercise of stock options within 60 days of December 31, 2019, 503 shares of common stock held by Mr. Powers and 250 shares of common stock held by Mr. Power's spouse.

(12) Includes 29,245 shares Ms. Lawley has the right to acquire through the exercise of stock options within 60 days of December 31, 2019.

(13) Includes 1,403,743 shares issuable pursuant to stock options and 3,991 RSUs that the executive officers and directors of the combined company have the right to acquire within 60 days of December 31, 2019.

(14) Consists of shares held by Deerfield Private Design Fund III, L.P. Deerfield Mgmt III, L.P. is the general partner of, and Deerfield Management Company, L.P. is the investment advisor to, Deerfield Private Design Fund III, L.P. Mr. James E. Flynn is the sole member of the general partner of each of Deerfield Mgmt III, L.P. and Deerfield Management Company, L.P. The address for each of these entities and Mr. Flynn is 780 Third Avenue, 37th Floor, New York, NY 10017.

(15) Address: 22555 Laredo Trail, Adel, Iowa 50003, Based solely upon a Schedule 13D filed with the SEC on October 6, 2017. Harry H. Stine, the CEO of Stine Seed Farm, Inc., may be deemed to beneficially own such shares.

(16) Consists of (i) 23,704 shares held by NEA Ventures 2013, L.P. ("Ven 2013") and (ii) 4,717,214 shares held by New Enterprise Associates 14, L.P. ("NEA 14") (collectively, the "NEA Shares"). The shares held by Ven 2013 are held indirectly by Karen P. Welsh, the general partner of Ven 2013. The shares held by NEA 14 are held indirectly by NEA Partners 14, L.P. ("NEA Partners 14"), the general partner of NEA 14, NEA 14 GP LTD ("NEA 14 LTD"), the general partner of NEA Partners 14, and the individual directors (the "Directors") of NEA 14 LTD. The Directors of NEA 14 LTD are Peter J. Barris, Forest Baskett, Anthony A. Florence, Patrick J. Kerins, David M. Mott, Scott D. Sandell, and Peter W. Sonsini. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their pecuniary interest therein. The address for each of these entities is c/o New Enterprise Associates, Inc., 1954 Greenspring Drive, Suite 600, Timonium, Maryland 21093.

(17) Consists of shares held by Clarus Lifesciences III, L.P. ("Clarus"). Clarus Ventures III GP, L.P. is the sole general partner of Clarus. Blackstone Clarus III L.L.C. is the sole general partner of Clarus Ventures III GP, L.P. The sole member of Blackstone Clarus III L.L.C. is Blackstone Holdings II L.P. The sole general partner of Blackstone Holdings II L.P. is Blackstone Holdings I/II GP Inc. The controlling shareholder of Blackstone Holdings I/II GP Inc. is The Blackstone Group L.P. The sole general partner of The Blackstone Group L.P. is Blackstone Group Management L.L.C. Blackstone Group Management L.L.C. is wholly-owned by The Blackstone Group L.P.'s senior managing directors and controlled by its founder, Stephen A. Schwarzman. Each of Clarus Ventures III GP, L.P., Blackstone Clarus III L.L.C., Blackstone Holdings II L.P., Blackstone Holdings I/II GP Inc., The Blackstone Group L.P., Blackstone Group Management L.L.C. and Stephen A. Schwarzman may be deemed to beneficially own the common stock beneficially owned by Clarus and each disclaim beneficial ownership of all shares held by Clarus. The address for the entities is 101 Main Street, Suite 1210, Cambridge, MA 02142.

WHERE YOU CAN FIND MORE INFORMATION

NewLink files annual, quarterly and current reports, proxy statements and other information with the SEC. NewLink's SEC filings are available to the public at the SEC's website at www.sec.gov.

Statements contained in this proxy statement, or in any document incorporated in this proxy statement by reference, regarding the contents of any contract or other document, are not necessarily complete, and each such statement is qualified in its entirety by reference to that contract or other document filed as an exhibit with the SEC. The SEC allows NewLink to "incorporate by reference" into this proxy statement documents NewLink files with the SEC. This means that NewLink can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be a part of this proxy statement. This proxy statement and the information that NewLink later files with the SEC may update and supersede the information incorporated by reference. Similarly, the information that NewLink later files with the SEC may update and supersede the information in this proxy statement.

NewLink also incorporates by reference the documents listed below and any documents filed by it pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this proxy statement and before the date of the Special Meeting (provided that NewLink is not incorporating by reference any information furnished to, but not filed with, the SEC):

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed on March 5, 2019;
- Our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2019 filed on May 8, 2019, ended June 30, 2019 filed on August 8, 2019, and ended September 30, 2019 filed on November 6, 2019; and
- Our Current Reports on Form 8-K filed on January 3, 2019, January 17, 2019, February 27, 2019, March 5, 2019, April 2, 2019, May 15, 2019, May 23, 2019, July 30, 2019, August 2, 2019, September 17, 2019, September 30, 2019, November 20, 2019 and December 20, 2019.

Copies of any of the documents NewLink files with the SEC may be obtained free of charge either on NewLink's website by contacting the Corporate Secretary by written request to NewLink Genetics Corporation, 2503 South Loop Drive, Ames, Iowa 50010 or by phone at (515) 598-2561.

If you would like to request documents from us, please do so at least five business days before the date of the special meeting in order to receive timely delivery of those documents prior to the special meeting.

THIS PROXY STATEMENT DOES NOT CONSTITUTE THE SOLICITATION OF A PROXY IN ANY JURISDICTION TO OR FROM ANY PERSON TO WHOM OR FROM WHOM IT IS UNLAWFUL TO MAKE SUCH PROXY SOLICITATION IN THAT JURISDICTION. YOU SHOULD RELY ONLY ON THE INFORMATION CONTAINED OR INCORPORATED BY REFERENCE IN THIS PROXY STATEMENT TO VOTE YOUR SHARES AT THE SPECIAL MEETING.

NEWLINK HAS NOT AUTHORIZED ANYONE TO PROVIDE YOU WITH INFORMATION THAT IS DIFFERENT FROM WHAT IS CONTAINED IN THIS PROXY STATEMENT. THIS PROXY STATEMENT IS DATED FEBRUARY 10, 2020. YOU SHOULD NOT ASSUME THAT THE INFORMATION CONTAINED IN THIS PROXY STATEMENT IS ACCURATE AS OF ANY DATE OTHER THAN THAT DATE, AND THE MAILING OF THIS PROXY STATEMENT TO STOCKHOLDERS SHALL NOT CREATE ANY IMPLICATION TO THE CONTRARY.

OTHER INFORMATION

Stockholder Communications with the NewLink Board

The NewLink Board has adopted a formal process by which stockholders may communicate with its board or any of its directors. This information is available on our website at *www.newlinkgenetics.com* in the "Investors & Media - Corporate Governance - Contact the Board" section.

Stockholder Proposals and Nominations of Directors

Stockholders who wish to submit a proposal for our 2020 Special Meeting of Stockholders must have submitted any such proposal by December 7, 2019, to Corporate Secretary, NewLink Genetics Corporation, 2503 South Loop Drive, Ames, Iowa 50010. If you wish to submit a director nomination or a proposal at next year's annual meeting that is not to be included in next year's proxy materials, you must do so by no later than the close of business on February 8, 2020, nor earlier than the close of business on January 9, 2020, and you must comply with the requirements of Section 5(b) in the our Bylaws, including submitting written notice to our Corporate Secretary as set forth above.

The Company has not yet selected the date of the annual meeting of stockholders for next year, but is considering holding the meeting in May 2020. If the date of the 2020 annual meeting is advanced or delayed more than 30 days before or after the anniversary of the date of this year's annual meeting, notice by the stockholder to be timely must be so received no earlier than the close of business on the 120th day prior to such 2020 annual meeting and not later than the close of business on the later of the 90th day prior to such 2020 annual meeting or the 10th day following the day on which public announcement of the date of such meeting is first made. Submissions must include the full name of the proposed nominee, a description of the proposed nominee's business experience for at least the previous five years, complete biographical information, a description of the proposed nominee's qualifications as a director, a representation that the nominating stockholder is a beneficial or record holder of our common stock and such other information as is required under Section 5(b) of our Bylaws. Any such submission must be accompanied by the written consent of the proposed nominee to be named as a nominee and to serve as a director if elected.

Householding of Proxy Materials

Some banks, brokers and other nominee record holders may be participating in the practice of "householding." This means that only one copy of this proxy statement may have been sent to multiple stockholders in a household. We will promptly deliver, upon oral or written request, a separate copy of the proxy statement to any stockholder residing at an address to which only one copy was mailed. Requests for additional copies should be directed in writing to a stockholder's broker, bank or other agent holding shares of our common stock for such stockholder or you may contact our principal executive offices at NewLink Genetics Corporation, 2503 South Loop Drive, Ames, Iowa 50010, Attention: Corporate Secretary or call (515) 598-2561. Stockholders wishing to receive separate copies of our proxy statements in the future, and stockholders sharing an address that wish to receive a single copy of our proxy statements if they are receiving multiple copies of our proxy statements, should contact his or her bank, broker or other agent record holder, or may contact our principal executive offices as described above.

INDEX TO FINANCIAL STATEMENTS OF LUMOS

Audited Financial Statements as of and for the Years Ended December 31, 2018 and 2017

Unaudited Financial Statements as of and for the Nine Months Ended September 30, 2019 and 2018

Independent Auditors' Report

The Board of Directors
Lumos Pharma, Inc.:

We have audited the accompanying financial statements of Lumos Pharma, Inc., which comprise the balance sheets as of December 31, 2018 and 2017, and the related statements of operations, changes in redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes to the financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with U.S. generally accepted accounting principles; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Lumos Pharma, Inc. as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended in accordance with U.S. generally accepted accounting principles.

KPMG LLP

Austin, Texas
August 15, 2019, except as to notes 2(j) and 13, which are as of November 12, 2019

LUMOS PHARMA, INC.
Balance Sheets
December 31, 2018 and 2017
(In thousands, except share and per share amounts)

	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 14,022	$ 24,679
Prepaid and other current assets	202	162
Total current assets	14,224	24,841
Property and equipment, net of accumulated depreciation and amortization of $124 and $93, respectively	112	144
Total assets	$ 14,336	$ 24,985
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		

Current liabilities:

Accounts payable
$
189

$
263

Accrued compensation

234

56

Other accrued liabilities

337

161

Total current liabilities

760

480

Total liabilities

760

480

Commitments and contingencies

Redeemable convertible preferred stock:			
Series B redeemable convertible preferred stock, par value $0.0001; 9,966,288 stock authorized, issued and outstanding as of December 31, 2018 and 2017; stated at accreted redemption value	39,592	37,553	
Series A redeemable convertible preferred stock, par value $0.0001; 11,204,513 stock authorized, issued and outstanding as of December 31, 2018 and 2017; stated at accreted redemption value	20,903	19,901	
Stockholders’ deficit:			
Common stock, $0.0001 par value; 36,000,000 shares authorized as of December 31, 2018 and 2017; and 10,283,437 and 10,083,437 shares issued and outstanding as of December 31, 2018 and 2017, respectively	1	1	
Additional paid-in capital	12	(221)	
Accumulated deficit	(46,932)	(32,729)	
Total stockholders’ deficit	(46,919)		

(32,949	
)	
Total liabilities, redeemable convertible preferred stock and stockholders’ deficit	
$	
14,336	
$	
24,985	

See accompanying notes to financial statements.

LUMOS PHARMA, INC.
Statements of Operations
Years ended December 31, 2018 and 2017
(In thousands)

	2018	2017
Operating expenses:		
Research and development	$ 5,253	$ 6,321
In-process research and development	3,500	—
General and administrative, including stock-based compensation of $199 and $187, respectively	2,533	2,676
Total operating expenses	11,286	8,997
Loss from operations	(11,286)	(8,997)
Other income, net:		
Interest and other income, net	124	51
Net loss		

$	
(11,162	
)	
$	
(8,946	
)	

See accompanying notes to financial statements.

LUMOS PHARMA, INC.
Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit
Years ended December 31, 2018 and 2017
(In thousands, except share amounts)

	Series A redeemable convertible preferred stock		Series B redeemable convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2016	9,966,288	$ 35,514			11,204,513	$ 18,899	$ 10,083,437	$ (408)	$ (20,742)	$ (21,149)
Net loss	—		—		—				

—

—

—

(8,946
)

(8,946
)

Stock-based compensation

—

—

—

—

—

—

187

—

187

Accretion of preferred stock to current redemption value

—

2,039

—

1,002

—

—

—

(3,041)													
(3,041)													
Balance, December 31, 2017	9,966,288		37,553		11,204,513		19,901		10,083,437		1		(221)
													(32,729)
													(32,949)
Exercise of common stock options	—		—		—		—		200,000		—		34
													—
													34
Net loss	—												

—

—

—

—

—

—

(11,162
)

(11,162
)
Stock-based compensation

—

—

—

—

—

—

199

—

199

Accretion of preferred stock to redemption value

—

2,039

—

1,002

—

—

—

(3,041
)

(3,041
)

Balance, December 31, 2018

9,966,288

$
39,592

11,204,513

$
20,903

10,283,437

$
1

$
12

$
(46,932
)

$
(46,919
)

See accompanying notes to financial statements.

LUMOS PHARMA, INC.
Statements of Cash Flows
Years ended December 31, 2018 and 2017
(In thousands)

	2018	2017
Cash flows from operating activities:		
Net loss	$ (11,162)	$ (8,946)
Adjustments to reconcile net loss to net cash used in operating activities:		
In-process research and development	3,500	—
Depreciation and amortization	33	39
Stock-based compensation	199	187
Changes in operating assets and liabilities:		
Other current assets	(40)	43
Accounts payable	(74	

)

(137
)
Accrued liabilities

354

(570
)
Net cash used in operating activities

(7,190
)

(9,384
)
Cash flows from investing activities:

Acquisition of in-process research and development

(3,500
)

—

Purchases of property and equipment

(1
)

(4
)
Net cash used in investing activities

(3,501
)

(4
)
Cash flows from financing activities:

Proceeds from exercise of common stock options

34

—

Net cash provided by financing activities

34

—

Net decrease in cash and cash equivalents	(10,657)	(9,388)
Cash and cash equivalents at beginning of period	24,679	34,067
Cash and cash equivalents at end of period	$ 14,022	$ 24,679

See accompanying notes to financial statements.

Notes to Financial Statements

(1) The Company

Lumos Pharma, Inc. ("Lumos" or the "Company") is a clinical-stage biopharmaceutical company focused on the identification, acquisition and in-license, development, and commercialization of novel products for the treatment of rare diseases. Lumos' mission is to develop new therapies for people with rare diseases, prioritizing its focus where the medical need is high, and the pathophysiology is clear. The Company's principal offices are located in Austin, Texas.

Since inception, the Company has devoted substantially all of its efforts and resources to identifying and developing its product candidates, recruiting personnel, and raising capital. The Company has never generated revenue and has not yet commenced commercial operations.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation

The accompanying financial statements of Lumos have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included.

(b) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Such management estimates include those related to accruals of research and development related expenses, fair value of common stock and stock-based compensation, and valuation of deferred tax assets. Actual results could differ significantly from those estimates.

(c) Risks and Uncertainties

The product candidates being developed by the Company require approvals from the U.S. Food and Drug Administration ("FDA") and/or foreign regulatory agencies prior to commercial sales. There can be no assurance that the Company's product candidates will receive the necessary approvals. If the Company is denied regulatory approval of its product candidates, or if approval is delayed, it may have a material adverse impact on the Company's business, results of operations, and its financial position.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery and development of drug candidates, raising additional capital, development of competing drugs and therapies, protection of proprietary technology and market acceptance of the Company's products. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company's future success.

(d) Concentrations of Credit Risk

The Company's cash and cash equivalents is held by a financial institution in the United States that potentially subjects the Company to a concentration of credit risk. The Company's cash deposits generally exceed federally insured limits. Management believes that the financial institution is financially sound and, accordingly, does not believe the Company is subject to substantial credit risk. The Company has not experienced any significant credit losses to date.

(e) Cash and Cash Equivalents

Cash and cash equivalents, which consist primarily of amounts held in checking, savings, and money market accounts, are stated at fair value. The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

(f) Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets which range from 3 to 8 years. Repairs and maintenance that do not extend the life or improve an asset are expensed as incurred. Upon retirement or sale, the cost of disposed assets and their related accumulated depreciation are removed from the balance sheet. Any gain or loss is credited or charged to operations.

(g) Impairment of Long-Lived Assets

The Company evaluates its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of these assets is measured by a comparison of their carrying amounts to future undiscounted cash flows the assets are expected to generate. If long-lived assets are considered to be impaired, the impairment to be recognized equals the amount by which the carrying value of the assets exceeds their fair value and is recorded in the period the determination is made. There was no impairment of long-lived assets in the years ended December 31, 2018 and 2017.

(h) Research and Development ("R&D") Expenses

R&D expenses are expensed as incurred. Amounts incurred in connection with license agreements are also included in R&D expense. Advance payments for goods or services to be rendered in the future for use in R&D activities are deferred and recorded as a prepaid asset. The deferred amounts are expensed as the related goods are delivered or the services are performed.

The Company records the expenses associated with research preclinical studies, clinical trials, and manufacturing development, as incurred. These expenses are a significant component of the Company's R&D expenses, as a substantial portion of the Company's ongoing R&D activities are conducted by third-party service providers.

(i) Asset Acquisition

The Company adopted ASU2017-01 in 2018 which resulted in the asset purchase agreement described in note 10(b)(iii) being accounted for as an asset purchase. The acquisition expense for the purchase of the In-Process Research and Development were expensed to R&D expenses in 2018. The Company has no reasonable expectation that there is an alternative future use of the asset purchased at this time and therefore, the purchase of the in-process R&D was immediately charged to expense.

(j) Series A and B Redeemable Convertible Preferred Stock

The Company accounts for its preferred stock subject to possible conversion in accordance with ASC 480, Distinguishing Liabilities from Equity ("ASC 480"). Stock subject to mandatory conversion (if any) is classified as a liability instrument and is measured at fair value. Conditionally convertible stock (including stock that features conversion rights that are either within the control of the holder or subject to conversion upon the occurrence of uncertain events not solely within the Company's control) is classified as temporary equity. At all other times, stock is classified as stockholders' equity. The Company's preferred stock features certain redemption rights that are considered by the Company to be outside of the Company's control and subject to the occurrence of uncertain future events.

Accordingly, at December 31, 2018 and 2017, the preferred stock subject to contingent redemption is presented as temporary equity, outside of the stockholders' deficit section of the Company's balance sheet. The carrying amount is at the issuance date fair value in accordance with ASR 268, Presentation in Financial Statements of Redeemable Preferred Stocks ("ASR 268") and adjusted to its maximum redemption amount due to its redemption features in accordance with ASC 480-10-S99-3A. The conversion feature of the Series A and Series B Redeemable Convertible preferred stock may be subject to certain antidilution provisions, which, if exercised, would require the Company to seek stockholder approval to increase the number of common shares authorized. For more information related to the redemption and conversion features of preferred stock, see Note 6.

(k) Stock-Based Compensation

The fair value of each option grant is estimated at the date of grant using the Black Scholes pricing model. Volatility is based on average historical volatilities for public companies in similar industries over the expected term of the option. The expected term of options represents the period of time that options granted are expected to be outstanding. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The Company utilized the probability weighted expected return method to estimate the fair value of each class of common and preferred stock. The valuation methodology included estimates and assumptions that require the Company's judgment. Significant inputs used to determine estimated fair value of the stocks include the equity value of the Company and expected timing of a liquidity event or other outcomes. Changes in these subjective unobservable inputs would result in an impact to the fair value measurement of the Company's shares and stock option fair value. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The Company recognizes the compensation expense either immediately or up to 4 years (the vesting periods) on a straight-line basis over the vesting period.

(l) Income Taxes

The Company accounts for deferred income taxes using the liability method. Under this method, deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. Temporary differences are then measured using the enacted tax rates and laws. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that is more likely than not to be realized. Determining the appropriate amount of valuation allowance requires management to exercise judgment about future operations.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on the technical merits, as the largest amount of benefits that is more likely than not to be realized upon the ultimate settlement. The Company's policy is to recognize interest and penalties related to the unrecognized tax benefits as a component of income tax expense. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

(3) New Accounting Pronouncements

(a) Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, Leases, which requires lessees to recognize right-of-use assets and liabilities on the balance sheet and disclose key information about leasing arrangements. Adoption of this standard is required beginning in the first quarter of 2021, and the Company anticipates adopting this standard on a modified retrospective basis, recognizing a cumulative-effect adjustment to the opening balance of retained earnings, if any, upon adoption. The Company continues to evaluate its contracts and other agreements to assess the impact this update will have on its financial statements, processes, policies and internal controls.

(b) Fair Value Measurement

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure for Fair Value Measurement ("ASU 2018-13"), which modifies the disclosure requirements on fair value measurements. ASU 2018-13 is effective for all entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, with partial early adoption permitted for eliminated disclosures. The method of adoption varies by the disclosure. The Company is currently evaluating the impact that adopting this guidance will have on the financial statements and related disclosures.

(c) Codification Improvements

In July 2018, the FASB issued ASU 2018-09, Codification Improvements ("ASU 2018-09"), which made minor amendments to the codification in order to correct errors, eliminate inconsistencies and provide clarifications in current guidance. ASU 2018-09 amends Subtopics 470-50, Debt Modifications and

Extinguishments, and 718-40, Compensation-Stock Compensation-Income Taxes, among other Topics amended within the update. Several of the Topics within the ASU were effective immediately upon issuance of ASU 2018-09, however, some amendments require transition guidance which is effective for nonpublic business entities for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact that adopting this guidance will have on the financial statements and related disclosures.

(d) Definition of a Business

In January 2017, the FASB issued ASU 2017-01, Business Combinations: Clarifying the Definition of a Business ("ASU 2017-01"), which amends the current definition of a business. Under ASU 2017-01, to be considered a business, an acquisition would have to include an input and substantive process that together significantly contributes to the ability to create outputs. ASU 2017-01 further states that when substantially all of the fair value of gross assets acquitted is concentrated in a single asset (or a group of similar assets), the assets acquired would not represent a business. The new guidance also narrows the definition of the term "outputs" to be consistent with how it is described in Topic 606, Revenue from Contracts with Customers. The change to the definition of a business will likely result in more acquisitions being accounted for as asset acquisitions. ASU 2017-01 is effective for acquisitions commencing on or after June 30, 2019, with early adoption permitted. The Company adopted ASU 2017-01 in 2018 which resulted in the asset purchase agreement described in 10(b)(iii) being accounted for as an asset purchase.

(4) Liquidity and Capital Resources

Since inception and as of December 31, 2018, the Company has incurred operating losses, has negative cash flows from operations and has no generated revenue. The Company expects to incur significant expenses, increased operating losses, and negative cash flows for the foreseeable future. The Company expects its expenses to increase in connection with conducting additional nonclinical studies, initiating clinical trials of its product candidates, seeking regulatory approval and marketing authorizations for its product candidates, and commercializing these product candidates, if approved. The Company may never achieve profitability and, as such, will need to raise additional capital. Accordingly, it will seek to fund its operations through public or private equity or debt financings, collaborations, grants, or other sources none of which can be assured, if and when necessary. The Company recorded net losses of $11.2 million and $8.9 million for the years ended December 31, 2018 and 2017, respectively. The Company had an accumulated deficit of $46.9 million and net working capital of $13.5 million as of December 31, 2018. The Company has funded its operations primarily through the sale and issuance of redeemable convertible preferred and common stock. As of December 31, 2018, the Company had cash and cash equivalents consisting of $14.0 million. The Company believes that its existing cash and cash equivalents will be sufficient to meet liquidity and capital requirements for at least one year from the issuance of these financial statements.

(5) Property and Equipment, Net

Property and equipment, net consist of the following (in thousands):

December 31	
2018	**2017**
Furniture and equipment	
$ 119	$ 120
Leasehold improvements	
64	64
Computer equipment	
49	49
Software	
4	4
Property and equipment, gross	

236

237

Less accumulated depreciation and amortization	(124)	(93)
Property and equipment, net	$ 112	$ 144

Depreciation and amortization expense was $33,076 and $38,952 for the years ended December 31, 2018 and 2017, respectively. All of the Company’s long-lived assets are located in the United States.

(6) Series A and Series B Redeemable Convertible Preferred Stock

In January 2014, the Company raised $6.5 million through the issuance of 4,353,928 shares of Series A Preferred Stock at $1.49 per share thru the “Initial Closing” of the Series A round. A “Second Closing” in May 2014 raised an additional $1.0 million through the issuance of 669,835 shares of Series A Preferred Stock at $1.49 per share.

In 2015, the Company raised an additional $3 million with a “Third Closing,” which was funded in three tranches through the issuance of a total of 1,826,823 shares of Series A Preferred Stock at $1.64 per share.

In December 2015, the Company received another $3.25 million of funding due to the trigger of milestone closing provisions of the Initial Closing agreement (“Milestone Closing”) and issued 2,176,963 shares of Series A Preferred Stock at $1.49 per share.

A second tranche of the Milestone Closing occurred in February 2016, and the Company issued 2,176,964 shares of Series A Preferred Stock at the issue price of $1.49 per share and received gross proceeds of $3.25 million.

In April 2016, the Company issued 9,966,288 shares of Series B Preferred Stock, par value $0.0001 per share, at an issuance price of $3.41 per share and received gross proceeds of $34.0 million. In connection with the financing, the Company incurred total issuance expenses of $298,000.

Series A and B Preferred Stock consist of the following (in thousands, except share amounts):

	December 31	
	2018	2017
Series B:		
Shares authorized	9,966,288	9,966,288
Shares outstanding	9,966,288	9,966,288
Liquidation preference	$ 39,592	$ 37,553
Series A:		
Shares authorized	11,204,513	

11,204,513

Shares outstanding

11,204,513

11,204,513

Liquidation preference
$
20,903

$
19,901

Significant provisions of the Series A and Series B Preferred Stock are as follows:

(a) Dividends

Series A Dividends: From the date of issuance of shares of Series A Preferred Stock, dividends shall accrue equal to 6% of the Original Issue Price. The Original Issue Price for the Series A Initial Closing, Second Closing, Third Closing, and Milestone Closing is $1.49 per share (“Series A Original Issue Price”).

Series B Dividends: The Company shall not pay any dividends on stock of any other class or series of stock in any calendar year unless the holders of shares of Series B Preferred Stock then outstanding shall first receive a dividend on each share of outstanding stock of Series B equal to 6% of the Original Issue Price. The Original Issue Price for the Series B is $3.41 per share (“Series B Original Issue Price”).

The Company has no obligation to pay such dividends except when, as and if declared by the board of directors (the “Board”). If after the dividends in the full preferential amount described above have been paid in any calendar year, the Board shall declare additional dividends, then such additional dividends shall be declared pro rata on the shares of common and preferred stock on a pari passu basis according to the number of shares of common stock held by such holders. For this purpose, each holder of shares of preferred stock is to be treated as holding the greatest whole number of shares of common stock then issuable upon conversion of all shares of preferred stock held by such holder. Since inception, the Company has not declared or paid any dividends.

(b) Voting

Each holder of outstanding shares of preferred stock has voting rights equal to an equivalent number of shares of common stock into which it is convertible and votes together as one class along with the common

stock. The holders of the shares of preferred stock have the right to vote on all significant matters as to which holders of shares of common stock have the right to vote.

For as long as at least 15% of the authorized shares of preferred stock remain outstanding, the Company must obtain the affirmative vote or written consent by at least a majority of the then outstanding shares of Series A or Series B Preferred Stock, along with Board consent to consummate significant transactions, including, but not limited to, the authorization and issuance of additional stock or stock classes, changing the legal form of the Company, and the approval of a deemed liquidation event.

(c) Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, the holders of shares of Series B Preferred Stock are entitled to be paid out of the assets of the Company before any payment shall be made to the holders of shares of Series A or common stock. The holders of the shares of Series B Preferred Stock shall receive the greater of i) the applicable Original Issue Price per share plus all unpaid accruing dividends, declared or not, on such shares of preferred stock or ii) the amount per share that would have been payable had all preferred stock been converted into common stock immediately prior to such liquidation, dissolution, or winding up. Liquidation payments to preferred stock-holders are payable in preference and priority to any payments made to the holders of the then outstanding shares of common stock and any equity securities ranking junior to the preferred stock.

(d) Redemption

Series A and B Redeemable Convertible Preferred Stock would be redeemed by the Company at a price per share equal to the Series A and Series B Redeemable Convertible Preferred Stock Original Issue Price plus all unpaid accruing dividends, declared or not, in three equal annual installments commencing not more than 60 days after the sixth anniversary of issuance of the shares of Series B Preferred Stock in April 2016, provided that the request is from the holders of a majority of the outstanding shares of preferred stock, including the holders of at least 32.3% of the outstanding shares of Series B Redeemable Convertible Preferred Stock for such redemption. Holders may elect a redemption request at any time after April 4, 2023 or upon a deemed liquidation event. The Company has classified the Series A and B Redeemable Convertible Preferred Stock as temporary equity outside of the Stockholders' Deficit based on the premise that these instruments provide the holder with the option to redeem at a determinable price, and have reflected the value to accreted redemption value at the end of the reporting period.

(e) Conversion

Each share of Series A and Series B Preferred Stock is convertible at the option of the holder, at any time into that number of fully paid and nonassessable shares of common stock determined by dividing the original issue price of the convertible preferred stock by the conversion price in effect on the date of conversion.

Conversion is automatic immediately upon i) the Company's sale of common stock in a firm commitment underwritten public offering of at least two times the Series B Original Issue Price (subject to adjustments for stock dividends, splits, combinations, and similar events) provided that the proceeds total at least $40,000,000, or ii) the election of the holders of a majority of the then outstanding shares of preferred stock.

(7) Common Stock

The following is a summary of the Company's common stock shares at December 31:

December 31	
2018	**2017**
Common stock:	
Shares authorized	
36,000,000	36,000,000
Shares outstanding	
10,283,437	10,083,437

The holders of common stock are entitled to receive distributions out of any assets legally available, subject to the prior rights and preferences of holders of all classes of shares outstanding.

(8) Stock-Based Compensation

In 2012, the Company adopted the Lumos Pharma, Inc. 2012 Equity Incentive Plan ("2012 Plan"), and in 2016 the Company adopted a 2016 Stock Plan ("2016 Plan"). The 2012 Plan and the 2016 Plan provide incentives to employees, consultants, and nonemployee directors of the Company by providing issuance of incentive stock options, nonstatutory stock options, stock appreciation rights, stock warrants, and restricted stock and incentive awards of common stock or any other class of equity authorized by the Company and designated by the board of directors as incentive equity.

In conjunction with the Series B offering, the maximum number of shares of common stock that can be issued were increased by 2,359,490, to a total of 3,711,490. The fixed stock reserve is 920,907 and 2,790,583 for the 2012 Plan and the 2016 Plan, respectively.

Common stock has been reserved for issuance as of December 31, 2018, of which 1,241,584 shares are available for future grants. The Company's stock options issued to date have variable vesting schedules, with a typical four years vesting schedule in which 25% of the stock vest on the one-year anniversary and vest over equal monthly installments thereafter. All awards expire ten years from the date of grant.

The fair value of each option grant is estimated at the date of grant using the Black Scholes pricing model with the following assumptions. Volatility is based on average historical volatilities for public companies in similar industries over the expected term of the option. The expected term of options represents the period of time that options granted are expected to be outstanding. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The Company utilized the probability weighted expected return method to estimate the fair value of each class of common and preferred share. The valuation methodology included estimates and assumptions that require the Company's judgment. Significant inputs used to determine estimated fair value of the shares include the equity value of the Company and expected timing of a liquidity event or other outcomes. Changes in these subjective unobservable inputs would result in an impact to the fair value measurement of the Company's shares and stock option fair value.

The weighted-average assumptions for 2018 and 2017 grants are provided in the following table:

	2018	2017
Valuation assumptions		
Expected dividend yield	0%	0%
Expected volatility	90%	90%
Expected term (years)	5.92	6.08
Risk-free interest rate	2.8%	2.1%

The following tables summarize stock option activity under the 2012 Plan and the 2016 Plan, which, to date, has consisted solely of equity classified grants of stock options to employees:

	Number of Shares	Weighted average exercise	Weighted average remaining	Aggregate intrinsic value

		price per share	contractual term (in years)	
Outstanding at December 31, 2016	2,204,858	$ 0.45	7.68	—
Granted	30,000	0.63		—
Forfeited	(75,995)	(0.16)		—
Outstanding at December 31, 2017	2,158,863	0.46	7.85	—
Options exercisable at December 31, 2017	1,337,107	$ 0.37	7.45	—

	Number of Shares	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2017	2,158,863	$ 0.46	7.85	—
Granted	473,252	0.32		—
Exercised	(200,000)	(0.17)		—
Forfeited	(245,646)	(0.18)		

—

Outstanding at December 31, 2018

2,186,469

0.49

7.67

—

Options exercisable at December 31, 2018

1,377,963

$
0.49

7.22

—

A summary of the status of the Company's nonvested shares as of December 31, 2018 and 2017, and changes during the years ended December 31, 2018 and 2017 is presented below:

Nonvested shares	Shares	Weighted average grant-date fair value
Balance at December 31, 2016	1,623,507	$ 0.56
Granted	30,000	0.63
Vested	(755,756)	(0.54)
Forfeited	(75,995)	(0.16)
Balance at December 31, 2017	821,756	$ 0.61

Nonvested shares		
Balance at December 31, 2017	821,756	$ 0.61
Granted	473,252	0.32
Vested	(486,502)	(0.54)
Balance at December 31, 2018	808,506	$ 0.48

Total stock-based compensation recognized from the Plan in the years ended December 31, 2018 and 2017, was $198,676 and $187,043, respectively, which is recorded as general and administrative expense in the statements of operations.

As of December 31, 2018, the total unrecognized compensation expense related to unvested employee awards was $351,509 which the Company expects to recognize over an estimated weighted average period of 2.49 years.

(9) Income Taxes

The differences between the actual income tax benefit and the amount computed by applying the statutory federal tax rate (21% for the year ended December 31, 2018 and 35% for the year ended December 31, 2017) to the loss before taxes are as follows (amounts in thousands):

	Year ended December 31,			
	2018		2017	
	Amount	Tax Rate	Amount	Tax Rate
Income tax benefit using statutory rate	$ (2,345)	21%	$ (3,130)	35%
Permanent differences	(5)	—	7	—
Change in tax rate	—	—	3,642	(41%)
Change in valuation allowance	2,350	(21%)	(519)	6%
Income tax expense (benefit)	$ —	—	$ —	—

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the carrying amounts used for income tax purposes. The components of deferred tax assets and liabilities are as follows (in thousands).

	As of December 31,	
	2018	2017
Deferred Tax Assets:		
Tax benefit of NOL carryforwards	$ 7,012	$ 5,379
Amortization of licenses	802	91
Other	7	7
Total deferred tax assets	7,821	5,477
Deferred tax liabilities	(7)	(13)
Net deferred tax assets	7,814	5,464
Valuation allowance for net deferred tax assets	(7,814)	(5,464)
Net deferred taxes		

$	
—	
$	
—	

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which temporary differences become deductible. Due to the uncertainty of the Company's ability to realize the benefit of the deferred tax assets, the net deferred tax assets are fully offset by a valuation allowance at December 31, 2018 and December 31, 2017.

At December 31, 2018, the Company had federal net operating loss ("NOL") carryforwards, which are available to offset future federal taxable income. The Company had $33.4 million and $25.6 million of federal net operating tax loss carryforwards as of December 31, 2018 and 2017, respectively. NOL carryforwards generated before January 1, 2018 will fully expire by 2038 unless utilized. NOLs generated in 2018 and later years have unlimited carryforward with an 80% of taxable income limitation. The Tax Cuts and Jobs Act (the "Act") was enacted on December 22, 2017. The Act reduces U.S. corporate rates from 35% to 21% for tax years beginning after December 31, 2017. As such, the estimated benefit of NOL carryforwards and other deferred tax assets were reduced offset by changes to the Company's valuation allowance.

However, as a result of prior changes in the ownership of the Company's capital stock, the NOL carryforwards may be subject to certain limitations under Section 382 of the Internal Revenue Code of 1986, as amended ("IRC Sec. 382"). To date, the Company has not engaged tax advisors to conduct a study of potential limitations of the NOL carryforwards under IRC Sec. 382, resulting from prior changes in the ownership of the Company's capital stock. Accordingly, there can be no assurance as to the extent, if any, that the NOL carryforwards will be available to offset future federal taxable income of the Company.

For the years ended December 31, 2018 and 2017, no amounts have been recognized for uncertain tax positions and no amounts have been assessed or recognized related to interest or penalties related to uncertain tax positions. The Company has determined that it is not reasonably likely for the amounts of unrecognized tax benefits to significantly increase or decrease within the next twelve months. The Company is currently subject to the general three-year statute of limitation for federal tax. Under this general rule, the earliest period subject to potential audit is 2015. For years in which the company may utilize its net operating losses, the IRS may examine the tax year that generated the losses and propose adjustments up to the amount of losses utilized.

(10) Research and License Agreements

(a) Grants and Awards

The Company was the recipient of an award from the Therapeutics for Rare and Neglected Diseases ("TRND") program of the National Institutes of Health ("NIH"). In cooperation with the Company, TRND has been supporting ongoing nonclinical development of cyclocreatine as a therapeutic for Creatine Transporter Deficiency ("CTD"). The award is a Cooperative Research and Development Agreement ("CRADA") whereby NIH provides in-kind contribution with staff and facilities, and was in effect through February 10, 2019.

(b) Development and License Agreements

(i) 2012 Settlement Agreement

The Company and certain executives and Board members were involved in litigation in the Federal District Court in Austin, Texas (the "Court"), with a former licensor, Avicena Group, Inc. ("Avicena") and its CEO from June 2011 until November 2012. The litigation was resolved by a binding settlement agreement (the "2012 Settlement Agreement") signed by the parties and an order of dismissal signed by the Court.

The 2012 Settlement Agreement imposes certain restrictions on the Company's right to develop or market therapies for use in connection with Parkinson's, Huntington's, ALS diseases, or skin care ailments, and its right to use creatine or its salts for any therapy, except CTD. The Company does not regard these restrictions as impediments to its ability to develop and market cyclocreatine as a drug therapy for CTD. In the 2012 Settlement Agreement, Avicena has agreed that for 25 years, it will not use, develop, or market cyclocreatine for any purpose.

(ii) University of Cincinnati License Agreement

In March 2012, the Company entered into a license agreement with the University of Cincinnati ("UC"). Under the terms of the License Agreement, UC granted the Company an exclusive worldwide license to develop, manufacture, and commercialize therapeutics related to UC's licensed products.

Under the License Agreement, the Company paid UC an up-front fee of $50,000, which was recorded as research and development expense in 2014. The annual license fees increasing from $2,000 in first, second, and third anniversaries (2013–2015) to $15,000 in the fourth (2016) and $30,000 in the fifth anniversary (2017–2018). The Company may be required to make future milestone payments contingent upon attainment of various development and regulatory approval milestones for the licensed product in any country. The milestone payments are payable in various amounts upon the start of different phases of clinical trials, application, and receipt of regulatory approval, with $50,000 upon completion of Phase II clinical study, $50,000 upon completion of a Phase III clinical study, and $150,000 upon FDA approval of a new drug application for a licensed product. Additionally, upon commercial sales of the product, the Company will be required to pay to UC a royalty on net sales of the licensed products in any country or region, if such product sales are ever achieved. The running royalty ranges from 2.5%–3.5% of net sales and also contains provisions for sublicense fees.

(iii) Merck License Agreement

In July 2018, the Company entered into an asset purchase agreement with Ammonett Pharma LLC ("Ammonett") to acquire assets of the company which comprised primarily of their license with Merck Sharp & Dohme Corp. ("Merck License") as well as related patents, intellectual property and related product inventory.

Under the purchase agreement, the Company paid Ammonett $3,500,000 which was recorded as research and development expense in 2018, as further described in notes 2(i) and 3(d). The Company may be required to make future milestone payments to both Ammonett and Merck contingent on achieving various development and regulatory approval milestones of approximately $14 million through approval of the first NDA for licensed product in the United States, as well as other milestones payments for major European countries and Japan. Additional milestone payments may be required if secondary indications are pursued. Upon commercial sales of the product, the Company will be required to pay milestone payments on gross annual net sales which range from $0 to $135 million. In addition, the Company would also pay royalties on net sales of the licensed products worldwide, if such product sales are ever achieved, of 10% to 12% of net sales.

(11) Related-Party Transactions

Pursuant to the Employment Agreements between the Company and its CEO and COO, if they are terminated by the Company without cause or they resign with good reason, then they are entitled to lump-sum payments as more fully set forth in the agreements. The COO was terminated as of December 31, 2017 and accordingly was paid the lump-sum of $154,500 in accordance with the agreement.

If the Company offers additional shares of equity in transactions for which the primary purpose is to raise capital, the Company's CEO has a preemptive right to subscribe to his pro rata share of equity securities granted upon the same terms that is offered to others, per his employment agreement, dated January 24, 2014.

The three independent directors on the Board receive compensation ranging from $30,000 to $36,000 per year for their services, payable quarterly.

(12) Commitments and Contingencies

In October 2014, the Company entered into a lease agreement for office space in Austin, Texas. The lease commenced in December 2014 and after the initial three-year term, the lease was extended for an additional two years in 2017 and for an additional two years in 2019 through November 30, 2021. The lease has rent escalation clauses through the lease term. The Company recognizes rent expense on a straight-line basis over the noncancelable term of the lease.

Under the terms of the Office Lease Agreement, the Company provided the lessor with a $14,980 security deposit. The lessor shall be entitled to retain all or any part of the security deposit for payment in the event of any uncured default by the Company under the terms of the lease.

As of December 31, 2018, the future minimum payments under noncancelable operating leases consist of $195,800, $203,800 and $195,300 for the years of 2019, 2020 and 2021, respectively.

For the years ended December 31, 2018 and 2017, the Company incurred $192,000 and $181,000, respectively, in rent expense under noncancelable operating leases.

The Company indemnifies each of its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of formation, and certificates of incorporation and bylaws. The term of the indemnification period lasts as long as an officer or a director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid.

(13) Subsequent Events

The Company evaluated subsequent events occurring after December 31, 2018 up to November 12, 2019 the date the financial statements were available to be issued. On September 30, 2019, the Company and NewLink Genetics Corporation ("NewLink"), Cyclone Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the NewLink (the "Merger Sub"), entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into the Company, with the Company surviving as a wholly-owned subsidiary of NewLink (the "Merger").

Immediately following the Merger, former Company stockholders will own approximately 50% of the aggregate number of NewLink common stock issued and outstanding following the consummation of the Merger (the "Post-Closing Stock"), and the stockholders of NewLink as of immediately prior to the Merger will own approximately 50% of the aggregate number of Post-Closing Stock.

Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of the Company and NewLink. The Merger Agreement contains certain termination rights for both the Company and NewLink, and further provides that, upon termination of the Merger Agreement under specified circumstances, the Company or NewLink, as applicable, may be required to pay the other party a termination fee of $2,000,000.

LUMOS PHARMA, INC.
Balance Sheets
(In thousands, except share and per share amounts)

Assets

	September 30, 2019 *(unaudited)*	**December 31, 2018**
Current assets:		
Cash and cash equivalents	$ 7,665	$ 14,022
Prepaid and other current assets	325	202
Total current assets	7,990	14,224
Property and equipment, net of accumulated depreciation and amortization of $146 and $124 respectively	89	112
Total assets	$ 8,079	$ 14,336

Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 396	$ 189
Accrued compensation	464	234
Accrued legal expenses	818	—
Other accrued liabilities	36	337
Total current liabilities	1,714	760
Total liabilities	1,714	760
Commitments and contingencies		
Redeemable convertible preferred stock:		
Series B redeemable convertible preferred shares, par value $0.0001; 9,966,288 shares authorized, issued and	41,117	39,592

outstanding as of September 30, 2019 and December 31, 2018; stated at accreted redemption value		
Series A redeemable convertible preferred shares, par value $0.0001; 11,204,513 shares authorized, issued and outstanding as of September 30, 2019 and December 31, 2018; stated at accreted redemption value	21,652	20,903
Stockholders' deficit:		
Common stock, $0.0001 par value; 36,000,000 shares authorized as of September 30, 2019 and December 31, 2018; and 8,933,537 and 10,283,437 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	1	1
Treasury stock, at cost, 1,350,000 shares held as of September 30, 2019, none held at December 31, 2018	—	—
Additional paid-in capital	144	12
Accumulated deficit	(56,549)	(46,932)
Total stockholders' deficit	(56,404)	(46,919)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 8,079	$ 14,336

See accompanying notes to the unaudited financial statements.

LUMOS PHARMA, INC.
Statements of Operations (unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2019	**2018**
Operating expenses:		
Research and development	$ 4,538	$ 4,126
In-process research and development	—	3,500
General and administrative, including stock-based compensation of $132 and $151, respectively	2,893	1,917
Total operating expenses	7,431	9,543
Loss from operations	(7,431)	(9,543)
Other income, net:		
Interest and other income, net	88	89

Net loss	$ (7,343)
	$ (9,454)

See accompanying notes to the unaudited financial statements.

LUMOS PHARMA, INC.
Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit (unaudited)
Nine months ended September 30, 2019
(In thousands, except share amounts)

	Series B redeemable convertible preferred stock		Series A redeemable convertible preferred stock		Common stock		Treasury stock, at cost		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2017	9,966,288	$ 37,553	11,204,513	$ 19,901	10,083,437	$ 1	—	$ —	$ (221)	$ (32,729)	$ (32,949)
Exercise of common stock options											

—

—

—

—

200,000

—

—

—

34

—

34

Net loss

—

—

—

—

—

—

—

—

—

—

(9,454
)

(9,454
)
Stock-based compensation

—

—

—

—

—

—

—

151

—

151

Accretion of preferred stock to current redemption value

—

1,525

—

749

—

—

—

—

—

(2,274
)

(2,274
)
Balance, September 30, 2018

9,966,288

39,078

11,204,513

20,650

10,283,437

1

—

—

(36
)

(44,457
)

(44,492
)
Net loss

—

—

—

—

—

—

—

—

—

(1,708
)

(1,708
)
Stock-based compensation

—

—

—

—

—

—

—

—

48

—

48

Accretion of preferred stock to current redemption value

—

514

—

253

—

—

—

—

(767)															
(767)															
Balance, December 31, 2018	9,966,288		39,592		11,204,513		20,903		10,283,437		1		—		—		12		(46,932)		(46,919)
Exercise of common stock options	—		—		—		—		100		—		—		—		—		—		—

—

—

—

Treasury stock purchase, at cost

—

—

—

—

(1,350,000
)

—

1,350,000

—

—

—

—

Net loss

—

—

—

—

—

—

—

—

—

—

(7,343
)

(7,343
)
Stock-based compensation

—

—

—

—

—

—

—

—

132

—

132

Accretion of preferred stock to current redemption value

—

1,525

—

749

—

—

—

—

—

(2,274
)

(2,274
)
Balance, September 30, 2019

9,966,288

$
41,117

11,204,513

$
21,652

8,933,537

$
1

1,350,000

$
—

$
144

$
(56,549
)
$
(56,404
)

See accompanying notes to the unaudited financial statements.

LUMOS PHARMA, INC.
Statements of Cash Flows (unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (7,343)	$ (9,454)
Adjustments to reconcile net loss to net cash used in operating activities:		
In-process research and development	—	3,500
Depreciation and amortization	23	25
Stock-based compensation	132	151
Changes in operating assets and liabilities:		
Other current assets	(123)	94
Accounts payable		

207

(77
)
Accrued liabilities

747

535

Net cash used in operating activities

(6,357
)

(5,226
)
Cash flows from investing activities:

Acquisition of in-process research and development

—

(3,500
)
Purchases of property and equipment

—

(2
)
Net cash used in investing activities

—

(3,502
)
Cash flows from financing activities:

Proceeds from exercise of common stock options

—

34

Treasury stock purchase, at cost

—

—		
Net cash provided by financing activities		
—		
34		
Net decrease in cash and cash equivalents		
(6,357)		
(8,694)		
Cash and cash equivalents at beginning of period		
14,022		
24,679		
Cash and cash equivalents at end of period		
$		
7,665		
$		
15,985		

See accompanying notes to the unaudited financial statements.

Notes to Unaudited Interim Financial Statements

(1) The Company

Lumos Pharma, Inc. ("Lumos" or the "Company") is a clinical-stage biopharmaceutical company focused on the identification, acquisition and in-license, development, and commercialization of novel products for the treatment of rare diseases. Lumos' mission is to develop new therapies for people with rare diseases, prioritizing its focus where the medical need is high, and the pathophysiology is clear. The Company's principal offices are located in Austin, Texas.

Since inception, the Company has devoted substantially all of its efforts and resources to identifying and developing its product candidates, recruiting personnel, and raising capital. The Company has never generated revenue and has not yet commenced commercial operations.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation

The accompanying unaudited condensed financial statements of Lumos Pharma, Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the nine-month period ended September 30, 2019 are not necessarily indicative of the results that may be expected for the year ended December 31, 2019.

(b) Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Such management estimates include those related to accruals of research and development related expenses, fair value of common stock and stock-based compensation, and valuation of deferred tax assets. Actual results could differ significantly from those estimates.

(c) Concentrations of Credit Risk

The Company's cash and cash equivalents is held by a financial institution in the United States that potentially subjects the Company to a concentration of credit risk. The Company's cash deposits generally exceed federally insured limits. Management believes that the financial institution is financially sound and, accordingly, does not believe the Company is subject to substantial credit risk. The Company has not experienced any significant credit losses to date.

(d) Cash and Cash Equivalents

Cash and cash equivalents, which consist primarily of amounts held in checking, savings, and money market accounts, are stated at fair value. The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

(e) Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from 3 to 8 years. Repairs and maintenance that do not extend the life or improve an asset are expensed as incurred. Upon retirement or sale, the cost of disposed assets and their related accumulated depreciation are removed from the balance sheet. Any gain or loss is credited or charged to operations.

(f) Impairment of Long-Lived Assets

The Company evaluates its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of these assets is measured by a comparison of their carrying amounts to future undiscounted cash flows the assets are expected to generate.

If long-lived assets are considered to be impaired, the impairment to be recognized equals the amount by which the carrying value of the assets exceeds their fair value and is recorded in the period the determination is made. There was no impairment of long-lived assets in the nine months ended September 30, 2019 and 2018.

(g) Research and Development ("R&D") Expenses

R&D expenses are expensed as incurred. Amounts incurred in connection with license agreements are also included in R&D expense. Advance payments for goods or services to be rendered in the future for use in R&D activities are deferred and recorded as a prepaid asset. The deferred amounts are expensed as the related goods are delivered or the services are performed.

The Company records the expenses associated with research preclinical studies, clinical trials, and manufacturing development, as incurred. These expenses are a significant component of the Company's R&D expenses, as a substantial portion of the Company's ongoing R&D activities are conducted by third-party service providers.

(h) Asset Acquisition

The Company adopted ASU2017-01 in 2018 which resulted in the asset purchase agreement described in note 10(b)(iii) being accounted for as an asset purchase. The acquisition expense for the purchase of the In-Process Research and Development were expensed to R&D expenses in 2018. The Company has no reasonable expectation that there is an alternative future use of the asset purchased at this time and therefore, the purchase of the in-process R&D was immediately charged to expense.

(i) Series A and B Redeemable Convertible Preferred Stock

The Company accounts for its preferred stock subject to possible conversion in accordance with ASC 480, Distinguishing Liabilities from Equity ("ASC 480"). Stock subject to mandatory conversion (if any) is classified as a liability instrument and is measured at fair value. Conditionally convertible stock (including stock that features conversion rights that are either within the control of the holder or subject to conversion upon the occurrence of uncertain events not solely within the Company's control) is classified as temporary equity. At all other times, stock is classified as stockholders' equity. The Company's preferred stock features certain redemption rights that are considered by the Company to be outside of the Company's control and subject to the occurrence of uncertain future events.

Accordingly, at September 30, 2019 and December 31, 2018, the preferred stock subject to contingent redemption is presented as temporary equity, outside of the stockholders' deficit section of the Company's balance sheet. The carrying amount is at the issuance date fair value in accordance with ASR 268, Presentation in Financial Statements of Redeemable Preferred Stocks ("ASR 268") and adjusted to its maximum redemption amount due to its redemption features in accordance with ASC 480-10-S99-3A. The conversion feature of the Series A and Series B Redeemable Convertible preferred stock may be subject to certain antidilution provisions, which, if exercised, would require the Company to seek stockholder approval to increase the number of common shares authorized. For more information related to the redemption and conversion features of preferred stock, see Note 6.

(j) Stock-Based Compensation

The fair value of each option grant is estimated at the date of grant using the Black Scholes pricing model. Volatility is based on average historical volatilities for public companies in similar industries over the expected term of the option. The expected term of options represents the period of time that options granted are expected to be outstanding. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The Company utilized the probability weighted expected return method to estimate the fair value of each class of common and preferred stock. The valuation methodology included estimates and assumptions that require the Company's judgment. Significant inputs used to determine estimated fair value of the stocks include the equity value of the Company and expected timing of a liquidity event or other outcomes. Changes in these subjective unobservable inputs would result in an impact to the fair value measurement of the Company's shares and

stock option fair value. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The Company recognizes the compensation expense either immediately or up to 4 years (the vesting periods) on a straight-line basis over the vesting period.

(k) Income Taxes

The Company accounts for deferred income taxes using the liability method. Under this method, deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. Temporary differences are then measured using the enacted tax rates and laws. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that is more likely than not to be realized. Determining the appropriate amount of valuation allowance requires management to exercise judgment about future operations.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on the technical merits, as the largest amount of benefits that is more likely than not to be realized upon the ultimate settlement. The Company's policy is to recognize interest and penalties related to the unrecognized tax benefits as a component of income tax expense. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

(3) New Accounting Pronouncements

(a) Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, Leases, which requires lessees to recognize right-of-use assets and liabilities on the balance sheet and disclose key information about leasing arrangements. Adoption of this standard is required beginning in the first quarter of 2021, and the Company anticipates adopting this standard on a modified retrospective basis, recognizing a cumulative-effect adjustment to the opening balance of retained earnings, if any, upon adoption. The Company continues to evaluate its contracts and other agreements to assess the impact this update will have on its financial statements, processes, policies and internal controls.

(b) Fair Value Measurement

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure for Fair Value Measurement ("ASU 2018-13"), which modifies the disclosure requirements on fair value measurements. ASU 2018-13 is effective for all entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, with partial early adoption permitted for eliminated disclosures. The method of adoption varies by the disclosure. The Company is currently evaluating the impact that adopting this guidance will have on the financial statements and related disclosures.

(c) Codification Improvements

In July 2018, the FASB issued ASU 2018-09, Codification Improvements ("ASU 2018-09"), which made minor amendments to the codification in order to correct errors, eliminate inconsistencies and provide clarifications in current guidance. ASU 2018-09 amends Subtopics 470-50, Debt Modifications and Extinguishments, and 718-40, Compensation-Stock Compensation-Income Taxes, among other Topics amended within the update. Several of the Topics within the ASU were effective immediately upon issuance of ASU 2018-09, however, some amendments require transition guidance which is effective for nonpublic business entities for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact that adopting this guidance will have on the financial statements and related disclosures.

(d) Definition of a Business

In January 2017, the FASB issued ASU 2017-01, Business Combinations: Clarifying the Definition of a Business ("ASU 2017-01"), which amends the current definition of a business. Under ASU 2017-01, to be considered a business, an acquisition would have to include an input and substantive process that

together significantly contributes to the ability to create outputs. ASU 2017-01 further states that when substantially all of the fair value of gross assets acquitted is concentrated in a single asset (or a group of similar assets), the assets acquired would not represent a business. The new guidance also narrows the definition of the term “outputs” to be consistent with how it is described in Topic 606, Revenue from Contracts with Customers. The change to the definition of a business will likely result in more acquisitions being accounted for as asset acquisitions. ASU 2017-01 is effective for acquisitions commencing on or after June 30, 2019, with early adoption permitted. The Company adopted ASU 2017-01 in 2018 which resulted in the asset purchase agreement described in 10(b)(iii) being accounted for as an asset purchase.

(4) Liquidity and Capital Resources

Since inception and as of September 30, 2019, the Company has incurred operating losses, has negative cash flows from operations and has no generated revenue. The Company expects to incur significant expenses, increased operating losses, and negative cash flows for the foreseeable future. The Company expects its expenses to increase in connection with conducting additional nonclinical studies, initiating clinical trials of its product candidates, seeking regulatory approval and marketing authorizations for its product candidates, and commercializing these product candidates, if approved. The Company may never achieve profitability and, as such, will need to raise additional capital. Accordingly, it will seek to fund its operations through public or private equity or debt financings, collaborations, grants, or other sources none of which can be assured, if and when necessary. The Company recorded net losses of $7.3 million and $9.5 million for the nine months ended September 30, 2019 and 2018, respectively. The Company had an accumulated deficit of $56.5 million and net working capital of $6.3 million as of September 30, 2019. The Company has funded its operations primarily through the sale and issuance of shares of redeemable convertible preferred and common stock. As of September 30, 2019, the Company had cash and cash equivalents consisting of $7.7 million. The Company believes that its existing cash and cash equivalents will be sufficient to meet liquidity and capital requirements for one year from the issuance of these financial statements.

(5) Property and Equipment, Net

Property and equipment, net consist of the following (in thousands):

	September 30, 2019	**December 31, 2018**
Furniture and equipment	$ 119	$ 119
Leasehold improvements	64	64
Computer equipment	48	49
Software	4	4
Property and equipment, gross	235	

236		
Less accumulated depreciation and amortization	(146)	(124)
Property and equipment, net	$ 89	$ 112

Depreciation and amortization expense was $22,911 and $24,843 for the nine months ended September 30, 2019 and 2018, respectively. All of the Company's long-lived assets are located in the United States.

(6) Series A and Series B Redeemable Convertible Preferred Stock

In January 2014, the Company raised $6.5 million through the issuance of 4,353,928 shares of Series A Preferred Stock at $1.49 per share thru the "Initial Closing" of the Series A round. A "Second Closing" in May 2014 raised an additional $1.0 million through the issuance of 669,835 shares of Series A Preferred Stock at $1.49 per share.

In 2015, the Company raised an additional $3 million with a "Third Closing," which was funded in three tranches through the issuance of a total of 1,826,823 shares of Series A Preferred Stock at $1.64 per share.

In December 2015, the Company received another $3.25 million of funding due to the trigger of milestone closing provisions of the Initial Closing agreement (Milestone Closing) and issued 2,176,963 shares of Series A Preferred Stock at $1.49 per share.

A second tranche of the Milestone Closing occurred in February 2016, and the Company issued 2,176,964 shares of preferred stock of Series A Preferred Stock at the issue price of $1.49 per share and received gross proceeds of $3.25 million.

In April 2016, the Company issued 9,966,288 shares of preferred stock of Series B Preferred Stock, par value $0.0001 per share, at an issuance price of $3.41 per share and received gross proceeds of $34.0 million. In connection with the financing, the Company incurred total issuance expenses of $298,000.

Series A and B Preferred Stock consist of the following (in thousands, except share amounts):

	September 30, 2019	**December 31, 2018**
Series B:		
Shares authorized	9,966,288	9,966,288
Shares outstanding	9,966,288	9,966,288
Liquidation preference	$ 41,117	$ 39,592
Series A:		
Shares authorized	11,204,513	11,204,513
Shares outstanding	11,204,513	11,204,513

11,204,513

Liquidation preference
$
21,652

$
20,903

Significant provisions of the Series A and Series B Preferred Stock are as follows:

(a) Dividends

Series A Dividends: From the date of issuance of shares of Series A Preferred Stock, dividends shall accrue equal to 6% of the Original Issue Price. The Original Issue Price for the Series A Initial Closing, Second Closing, Third Closing, and Milestone Closing is $1.49 per share, ("Series A Original Issue Price").

Series B Dividends: The Company shall not pay any dividends on stock of any other class or series of stock in any calendar year unless the holders of shares of Series B Preferred Stock then outstanding shall first receive a dividend on each share of outstanding stock of Series B equal to 6% of the Original Issue Price. The Original Issue Price for the Series B is $3.41 per share ("Series B Original Issue Price").

The Company has no obligation to pay such dividends except when, as and if declared by the board of directors (the "Board"). If after the dividends in the full preferential amount described above have been paid in any calendar year, the Board shall declare additional dividends, then such additional dividends shall be declared pro rata on the shares of common and preferred stock on a pari passu basis according to the number of shares of common stock held by such holders. For this purpose, each holder of shares of preferred stock is to be treated as holding the greatest whole number of shares of common stock then issuable upon conversion of all shares of preferred stock held by such holder. Since inception, the Company has not declared or paid any dividends.

(b) Voting

Each holder of outstanding shares of preferred stock has voting rights equal to an equivalent number of shares of common stock into which it is convertible and votes together as one class along with the common stock. The holders of the preferred stock have the right to vote on all significant matters as to which holders of shares of common stock have the right to vote.

For as long as at least 15% of the authorized shares of preferred stock remain outstanding, the Company must obtain the affirmative vote or written consent by at least a majority of the then outstanding shares of Series A or Series B Preferred Stock, along with Board consent to consummate significant transactions, including, but not limited to, the authorization and issuance of additional stock or stock classes, changing the legal form of the Company, and the approval of a deemed liquidation event.

(c) Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, the holders of shares of Series B Preferred Stock are entitled to be paid out of the assets of the Company before

any payment shall be made to the holders of shares of Series A or common stock. The holders of the shares of Series B Preferred Stock shall receive the greater of i) the applicable Original Issue Price per share plus all unpaid accruing dividends, declared or not, on such shares of preferred stock or ii) the amount per share that would have been payable had all preferred stock been converted into common stock immediately prior to such liquidation, dissolution, or winding up. Liquidation payments to preferred stockholders are payable in preference and priority to any payments made to the holders of the then outstanding shares of common stock and any equity securities ranking junior to the preferred stock.

(d) Redemption

Series A and B Redeemable Convertible Preferred Stock would be redeemed by the Company at a price per share equal to the Series A and Series B Redeemable Convertible Preferred Stock Original Issue Price plus all unpaid accruing dividends, declared or not, in three equal annual installments commencing not more than 60 days after receiving request from holders, provided that the request is from the holders of a majority of the outstanding shares of preferred stock, including the holders of at least 32.3% of the outstanding shares of Series B Redeemable Convertible Preferred Stock for such redemption. Holders may elect a redemption request at any time after April 4, 2023 or upon a deemed liquidation event. The Company has classified the Series A and B Redeemable Convertible Preferred Stock as temporary equity outside of the Stockholders' Deficit based on the premise that these instruments provide the holder with the option to redeem at a determinable price, and have reflected the value to accreted redemption value at the end of the reporting period.

(e) Conversion

Each share of Series A and Series B Preferred Stock is convertible at the option of the holder, at any time into that number of fully paid and nonassessable shares of common stock determined by dividing the original issue price of the convertible preferred stock by the conversion price in effect on the date of conversion.

Conversion is automatic immediately upon i) the Company's sale of common stock in a firm commitment underwritten public offering of at least two times the Series B Original Issue Price (subject to adjustments for stock dividends, splits, combinations, and similar events) provided that the proceeds total at least $40,000,000, or ii) the election of the holders of a majority of the then outstanding preferred stock.

(7) Common Stock

The following is a summary of the Company's common stock:

	September 30, 2019	**December 31, 2018**
Common stock:		
Shares authorized	36,000,000	36,000,000
Shares outstanding	8,933,537	10,283,437
Treasury stock	1,350,000	—

The holders of common stock are entitled to receive distributions out of any assets legally available, subject to the prior rights and preferences of holders of all classes of shares outstanding.

On September 27, 2019, the Company repurchased 1,350,000 common stock from two stockholders for $20 in total. The repurchase was in conjunction with the anticipated Merger described in note 13. If the merger is not consummated, the repurchased shares will be returned to the stockholders from which the shares were purchased without additional consideration.

(8) Stock-Based Compensation

In 2012, the Company adopted the Lumos Pharma, Inc. 2012 Equity Incentive Plan ("2012 Plan"), and in 2016 the Company adopted a 2016 Stock Plan ("2016 Plan"). The 2012 Plan and 2016 Plan provide incentives to employees, consultants, and nonemployee directors of the Company by providing issuance of incentive stock options, nonstatutory stock options, stock appreciation rights, stock warrants, and restricted stock and incentive awards of common stock or any other class of equity authorized by the Company and designated by the board of directors as incentive equity.

In conjunction with the Series B offering, the maximum number of shares of common stock that can be issued were increased by 2,359,490, to a total of 3,711,490. The fixed stock reserve is 920,907 and 2,790,583 for the 2012 Plan and 2016 Plan, respectively.

Common stock has been reserved for issuance as of September 30, 2019, of which 1,197,963 shares are available for future grants. The Company's stock options issued to date have variable vesting schedules, with a typical four years vesting schedule in which 25% of the stock vest on the one-year anniversary and vest over equal monthly installments thereafter. All awards expire ten years from the date of grant.

The fair value of each option grant is estimated at the date of grant using the Black Scholes pricing model with the following assumptions. Volatility is based on average historical volatilities for public companies in similar industries over the expected term of the option. The expected term of options represents the period of time that options granted are expected to be outstanding. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The Company utilized the probability weighted expected return method to estimate the fair value of each class of common and preferred share. The valuation methodology included estimates and assumptions that require the Company's judgment. Significant inputs used to determine estimated fair value of the shares include the equity value of the Company and expected timing of a liquidity event or other outcomes. Changes in these subjective unobservable inputs would result in an impact to the fair value measurement of the Company's shares and stock option fair value.

The weighted-average assumptions for grants are provided in the following table:

	Nine months ended September 30,	
	2019	**2018**
Valuation assumptions		
Expected dividend yield	0%	0%
Expected volatility	90%	90%
Expected term (years)	6.02	5.92
Risk-free interest rate	1.80%	2.80%

The following tables summarize stock option activity under the 2012 Plan and 2016 Plan, which, to date, has consisted solely of equity classified grants of stock options to employees:

	Number of Shares	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2017	2,158,863	$ 0.46	7.85	—
Granted	473,252	0.65		—

Exercised	(200,000)	(0.17)		—
Forfeited	(245,646)	(0.18)		—
Outstanding at September 30, 2018	2,186,469	0.49	7.67	—
Options exercisable at September 30, 2018	1,243,593	$ 0.49	7.13	—

	Number of Shares	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2018	2,186,469	$ 0.49	7.67	—
Granted	200,000	0.24		—
Exercised	(100)	(0.63)		—
Forfeited	(156,379)	(0.55)		—
Outstanding at September 30, 2019	2,229,990	0.46	7.15	—
Options exercisable at September 30, 2019	1,760,022	$ 0.47	6.11	—

A summary of the status of the Company's nonvested shares as of September 30, 2019 and 2018, and changes during the nine months ended September 30, 2019 and 2018 is presented below:

	Shares	Weighted average grant-date fair value
Nonvested shares		
Balance at December 31, 2017	821,756	$ 0.61
Granted	473,252	0.65
Vested	(352,132)	(0.54)
Balance at September 30, 2018	942,876	$ 0.49

	Shares	Weighted average grant-date fair value
Nonvested shares		
Balance at December 31, 2018	808,506	$ 0.48
Granted		

200,000

0.24

Vested

(382,159
)

(0.48
)
Forfeited

(156,379
)

(0.55
)
Balance at September 30, 2019

469,968

$
0.35

Total stock-based compensation recognized from the Plan in the nine months ended September 30, 2019 and 2018, was $132,958 and $151,071, respectively, which is recorded as general and administrative expense in the statements of operations.

As of September 30, 2019, the total unrecognized compensation expense related to unvested employee awards was $178,119 which the Company expects to recognize over an estimated weighted average period of 2.73 years. The weighted average contractual life of the options is 7.15 years as of September 30, 2019.

(9) Income Taxes

The differences between the actual income tax benefit and the amount computed by applying the statutory federal tax rate (21% for the nine months ended September 30, 2019 and 2018) to the loss before taxes are as follows (amounts in thousands):

	Nine months ended September 30,			
	2019		2018	
	Amount	Tax Rate	Amount	Tax Rate
Income tax benefit using statutory rate	$ (1,542)	21%	$ (1,986)	21%
Permanent differences	187	(3%)	5	—
Return to provision adjustments	(4)	—	—	—
Change in valuation allowance	1,359	(18%)	1,981	(21%)
Income tax expense (benefit)	$ —	—	$ —	—

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the carrying amounts used for income tax purposes. The components of deferred tax assets and liabilities are as follows (in thousands):

	As of September 30, 2019	As of December 31, 2018
Deferred Tax Assets:		
Tax benefit of NOL carryforwards	$ 8,309	$ 7,012
Amortization of licenses	748	802
Other	124	7
Total deferred tax assets	9,181	7,821
Deferred tax liabilities	(8)	(7)
Net deferred tax assets	9,173	7,814
Valuation allowance for net deferred tax	(9,173)	(7,814)
Net deferred taxes	$ —	$ —

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which temporary differences become deductible. Due to the uncertainty of the Company's ability to realize the benefit of the deferred tax assets, the net deferred tax assets are fully offset by a valuation allowance at September 30, 2019 and September 30, 2018.

At September 30, 2019, the Company had federal net operating loss ("NOL") carryforwards of approximately $39.6 million which are available to offset future federal taxable income and begin to expire in the year 2028. NOL carryforwards generated before January 1, 2018 will fully expire by 2038 unless utilized. NOLs generated in 2018 and later years have unlimited carryforward with an 80% of taxable income limitation. The Tax Cuts and Jobs Act (the "Act") was enacted on December 22, 2017. The Act reduces U.S. corporate rates from 35% to 21% for tax years beginning after December 31, 2017. As such, the estimated benefit of NOL carryforwards and other deferred tax assets were reduced offset by changes to the Company's valuation allowance.

However, as a result of prior changes in the ownership of the Company's capital stock, the NOL carryforwards may be subject to certain limitations under Section 382 of the Internal Revenue Code of 1986, as amended ("IRC Sec. 382"). To date, the Company has not engaged tax advisors to conduct a study of potential limitations of the NOL carryforwards under IRC Sec. 382, resulting from prior changes in the ownership of the Company's capital stock. Accordingly, there can be no assurance as to the extent, if any, that the NOL carryforwards will be available to offset future federal taxable income of the Company.

For the nine months ended September 30, 2019 and 2018, no amounts have been recognized for uncertain tax positions and no amounts have been assessed or recognized related to interest or penalties related to uncertain tax positions. The Company has determined that it is not reasonably likely for the amounts of unrecognized tax benefits to significantly increase or decrease within the next twelve months. The Company is currently subject to the general three-year statute of limitation for federal tax. Under this general rule, the earliest period subject to potential audit is 2015. For years in which the company may utilize its net operating losses, the IRS may examine the tax year that generated the losses and propose adjustments up to the amount of losses utilized.

(10) Research and License Agreements

(a) Grants and Awards

The Company was the recipient of an award from the Therapeutics for Rare and Neglected Diseases ("TRND") program of the National Institutes of Health ("NIH"). In cooperation with the Company, TRND has been supporting ongoing nonclinical development of cyclocreatine as a therapeutic for Creatine Transporter Deficiency ("CTD"). The award is a Cooperative Research and Development Agreement ("CRADA") whereby NIH provides in-kind contribution with staff and facilities, and was in effect through February 10, 2019.

(b) Development and License Agreements

(i) 2012 Settlement Agreement

The Company and certain executives and Board members were involved in litigation in the Federal District Court in Austin, Texas (the "Court"), with a former licensor, Avicena Group, Inc. ("Avicena") and its CEO from June 2011 until November 2012. The litigation was resolved by a binding settlement agreement (the "2012 Settlement Agreement") signed by the parties and an order of dismissal signed by the Court.

The 2012 Settlement Agreement imposes certain restrictions on the Company's right to develop or market therapies for use in connection with Parkinson's, Huntington's, ALS diseases, or skin care ailments, and its right to use creatine or its salts for any therapy, except CTD. The Company does not regard these restrictions as impediments to its ability to develop and market cyclocreatine as a drug therapy for CTD. In the 2012 Settlement Agreement, Avicena has agreed that for 25 years, it will not use, develop, or market cyclocreatine for any purpose.

(ii) University of Cincinnati License Agreement

In March 2012, the Company entered into a license agreement with the University of Cincinnati ("UC"). Under the terms of the License Agreement, UC granted the Company an exclusive worldwide license to develop, manufacture, and commercialize therapeutics related to UC's licensed products.

Under the License Agreement, the Company paid UC an up-front fee of $50,000, which was recorded as research and development expense in 2014. The annual license fees increasing from $2,000 in first, second, and third anniversaries (2013–2015) to $15,000 in the fourth (2016) and $30,000 in the fifth anniversary (2017- 2018). The Company may be required to make future milestone payments contingent upon attainment of various development and regulatory approval milestones for the licensed product in any country. The milestone payments are payable in various amounts upon the start of different phases of clinical trials, application, and receipt of regulatory approval, with $50,000 upon completion of Phase II clinical study, $50,000 upon completion of a Phase III clinical study, and $150,000 upon FDA approval of a new drug application for a licensed product. Additionally, upon commercial sales of the product, the Company will be required to pay to UC a royalty on net sales of the licensed products in any country or region, if such product sales are ever achieved. The running royalty ranges from 2.5%–3.5% of net sales and also contains provisions for sublicense fees.

This agreement was terminated on October 25, 2019 which included a mutual release of all claims under the License Agreement.

(iii) Merck License Agreement

In July 2018, the Company entered into an asset purchase agreement with Ammonett Pharma LLC (“Ammonett”) to acquire assets of the company which comprised primarily of their license with Merck Sharpe & Dohme Corp. (Merck License) as well as related patents, intellectual property and related product inventory.

Under the purchase agreement, the Company paid Ammonett $3,500,000 which was recorded as research and development expense in 2018, as further described in notes 2(h) and 3(d). The Company may be required to make future milestone payments to both Ammonett and Merck contingent on achieving various development and regulatory approval milestones of approximately $14 million through approval of the first NDA for licensed product in the United States, as well as other milestones payments for major European countries and Japan. Additional milestone payments may be required if secondary indications are pursued. Upon commercial sales of the product, the Company will be required to pay milestone payments on gross annual net sales which range from $0 to $135 million. In addition, the Company would also pay royalties on net sales of the licensed products worldwide, if such product sales are ever achieved, of 10% to 12% of net sales.

(iv) Vigilan Transfer Agreement

The Company has been conducting a natural history study (“Vigilan”) in conjunction with the NIH and certain hospitals in the United States. Pursuant to a letter of agreement, Vigilan is being transferred to another biopharmaceutical company with an ongoing program to target related patients. The transition is anticipated to be complete prior to the end of 2019 and no further costs for such study will be incurred by the Company.

(11) Related-Party Transactions

Pursuant to the Employment Agreements between the Company and its CEO and COO, if they are terminated by the Company without cause or they resign with good reason, then they are entitled to lump-sum payments as more fully set forth in the agreements. The COO was terminated as of December 31, 2017 and accordingly was paid the lump-sum of $154,500 in accordance with the agreement.

If the Company offers additional shares of equity in transactions for which the primary purpose is to raise capital, the Company’s CEO has a preemptive right to subscribe to his pro rata share of equity securities granted upon the same terms that is offered to others, per his employment agreement, dated January 24, 2014.

The three independent directors on the Board receive compensation ranging from $30,000 to $36,000 per year for their services, payable quarterly.

(12) Commitments and Contingencies

In October 2014, the Company entered into a lease agreement for office space in Austin, Texas. The lease commenced in December 2014 and after the initial three-year term, the lease was extended for an additional two

years in 2017 and for an additional two years in 2019 through November 30, 2021. The lease has rent escalation clauses through the lease term. The Company recognizes rent expense on a straight-line basis over the noncancelable term of the lease.

Under the terms of the Office Lease Agreement, the Company provided the lessor with a $14,980 security deposit. The lessor shall be entitled to retain all or any part of the security deposit for payment in the event of any uncured default by the Company under the terms of the lease.

As of September 30, 2019, the future minimum payments under noncancelable operating leases consist of $49,400, $203,800 and $195,300 for the years of 2019, 2020 and 2021, respectively.

For the nine months ended September 30, 2019 and 2018, the Company incurred $144,000 and $144,000, respectively, in rent expense under noncancelable operating leases.

The Company indemnifies each of its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of formation, and certificates of incorporation and bylaws. The term of the indemnification period lasts as long as an officer or a director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid.

(13) Merger Agreement

On September 30, 2019, the Company and NewLink Genetics Corporation ("NewLink"), Cyclone Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the NewLink (the "Merger Sub"), entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into the Company, with the Company surviving as a wholly-owned subsidiary of NewLink (the "Merger").

Immediately following the Merger, former Company stockholders will own approximately 50% of the aggregate number of NewLink common stock issued and outstanding following the consummation of the Merger (the "Post-Closing Stock"), and the stockholders of NewLink as of immediately prior to the Merger will own approximately 50% of the aggregate number of Post-Closing Stock.

Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of the Company and NewLink. The Merger Agreement contains certain termination rights for both the Company and NewLink, and further provides that, upon termination of the Merger Agreement under specified circumstances, the Company or NewLink, as applicable, may be required to pay the other party a termination fee of $2,000,000.

(14) Subsequent Events

The Company evaluated subsequent events occurring after September 30, 2019 up to November 12, 2019 the date the financial statements were available to be issued.

Annex A

EXECUTION VERSION

AGREEMENT AND PLAN OF MERGER AND REORGANIZATION

among:

NEWLINK GENETICS CORPORATION,
a Delaware corporation;

CYCLONE MERGER SUB, INC.,
a Delaware corporation; and

LUMOS PHARMA, INC.,
a Delaware corporation

Dated as of September 30, 2019

This document is intended solely for discussion purposes. It is not intended to create, and will not be deemed to create, a legally binding or enforceable agreement of any type or nature prior to the duly authorized and approved execution of this document by all parties and the delivery of an executed copy hereof by all parties to all other parties.

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AGREEMENT AND PLAN OF MERGER AND REORGANIZATION

THIS AGREEMENT AND PLAN OF MERGER AND REORGANIZATION (this "***Agreement***") is made and entered into as of September 30, 2019, by and among **NewLink Genetics Corporation**, a Delaware corporation ("Parent"), **Cyclone Merger Sub, Inc.**, a Delaware corporation and wholly owned subsidiary of Parent ("Merger Sub"), and **Lumos Pharma, Inc.**, a Delaware corporation (the "***Company***"). Certain capitalized terms used in this Agreement are defined in **Exhibit A**.

RECITALS

A. Parent and the Company intend to effect a merger of Merger Sub with and into the Company (the "***Merger***") in accordance with this Agreement and the DGCL. Upon consummation of the Merger, Merger Sub will cease to exist and the Company will become a wholly owned subsidiary of Parent.

B. The Parties intend that the Merger qualifies as a "reorganization" within the meaning of Section 368(a) of the Code, and by executing this Agreement, the Parties intend to adopt a plan of reorganization within the meaning of Treasury Regulations Sections 1.368-2(g) and 1.368-3.

C. The Parent Board has (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of Parent and its stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions, including the issuance of shares of the Parent Common Stock to the stockholders of the Company pursuant to the terms of this Agreement and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of Parent vote to approve the Parent Stockholder Matters.

D. The Merger Sub Board has (i) determined that the Contemplated Transactions are fair to, advisable, and in the best interests of Merger Sub and its sole stockholder, (ii) approved and declared advisable this Agreement and the Contemplated Transactions and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholder of Merger Sub votes to adopt this Agreement and thereby approve the Contemplated Transactions.

E. The Company Board has (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of the Company and its stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of the Company vote to approve the Company Stockholder Matters.

F. Concurrently with the execution and delivery of this Agreement and as a condition and inducement to Parent's willingness to enter into this Agreement, the officers, directors and stockholders of the Company listed on Section A of the Company Disclosure Schedule (solely in their capacity as stockholders of the Company) (the "Company Signatories") are executing lock-up agreements in substantially the form attached hereto as **Exhibit B** executed by the Company Signatories (each, a "***Company Lock-Up Agreement***").

G. Concurrently with the execution and delivery of this Agreement and as a condition and inducement to the Company's willingness to enter into this Agreement, the officers, directors and stockholder of Parent listed on Section A of the Parent Disclosure Schedule (solely in their capacity as stockholders of Parent) are executing (a) support agreements in favor of the Company in substantially the form attached hereto as **Exhibit C** (the "***Parent Stockholder Support Agreement***"), pursuant to which such Persons (the "***Parent Signatories***") have, subject to the terms and conditions set forth therein, agreed to vote all of their shares of Parent Common Stock in favor of the Parent Stockholder Matters and against any proposals that compete with the Contemplated Transactions and (b) lock-up agreements in substantially the form attached hereto as **Exhibit B** executed by the Parent Signatories (each, a "***Parent Lock-Up Agreement***").

H. It is expected that immediately after the execution of this Agreement, the Company shall deliver the Company Stockholder Written Consent evidencing the Required Company Stockholder Vote.

AGREEMENT

The Parties, intending to be legally bound, agree as follows:

Section 1. DESCRIPTION OF TRANSACTION

1.1 **The Merger**. Upon the terms and subject to the conditions set forth in this Agreement, at the Effective Time, Merger Sub shall be merged with and into the Company, and the separate existence of Merger Sub shall cease. The Company will continue as the surviving corporation in the Merger (the "***Surviving Corporation***").

1.2 **Effects of the Merger**. The Merger shall have the effects set forth in this Agreement, the Certificate of Merger and in the applicable provisions of the DGCL. As a result of the Merger, the Company will become a wholly owned subsidiary of Parent.

1.3 **Closing; Effective Time**. Unless this Agreement is earlier terminated pursuant to the provisions of Section 9.1, and subject to the satisfaction or waiver of the conditions set forth in Sections 6, 7 and 8, the consummation of the Merger (the "***Closing***") shall take place remotely as promptly as practicable (but in no event later than the second Business Day following the satisfaction or waiver of the last to be satisfied or waived of the conditions set forth in Sections 6, 7 and 8, other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction or waiver of each of such conditions), or at such other time, date and place as Parent and the Company may mutually agree in writing. The date on which the Closing actually takes place is referred to as the "Closing Date." At the Closing, the Parties shall cause the Merger to be consummated by executing and filing with the Secretary of State of the State of Delaware a certificate of merger with respect to the Merger, satisfying the applicable requirements of the DGCL and in a form reasonably acceptable to Parent and the Company (the "***Certificate of Merger***"). The Merger shall become effective at the time of the filing of such Certificate of Merger with the Secretary of State of the State of Delaware or at such later time as may be specified in such Certificate of Merger with the consent of Parent and the Company (the time as of which the Merger becomes effective being referred to as the "***Effective Time***").

1.4 **Certificate of Incorporation and Bylaws; Directors and Officers**. At the Effective Time:

(a) the certificate of incorporation of the Surviving Corporation shall be amended and restated in its entirety to read identically to the certificate of incorporation of Merger Sub as in effect immediately prior to the Effective Time, until thereafter amended as provided by the DGCL and such certificate of incorporation; *provided*, *however*, that at the Effective Time (as part of the Certificate of Merger), the Surviving Company's certificate of incorporation shall be amended to (i) change the name of the Surviving Corporation to a name mutually agreed upon by Parent and the Company and (ii) make such other changes as are mutually agreed to by Parent and the Company;

(b) the certificate of incorporation of Parent shall be identical to the certificate of incorporation of Parent immediately prior to the Effective Time, until thereafter amended as provided by the DGCL and such certificate of incorporation, *provided*, *however*, that following the Effective Time, Parent shall file an amendment to its certificate of incorporation to (i) change the name of Parent to Lumos Pharma, Inc., (ii) as contemplated by Section 5.3(a)(i), effect the Nasdaq Reverse Split and (iii) make such other changes as are mutually agreeable to Parent and the Company;

(c) the bylaws of the Surviving Corporation shall be amended and restated in their entirety to read identically to the bylaws of Merger Sub as in effect immediately prior to the Effective Time (except that the name of the Surviving Corporation in such bylaws shall reflect the name identified in Section 1.4(a)), until thereafter amended as provided by the DGCL and such bylaws;

(d) the directors and officers of Parent, each to hold office in accordance with the certificate of incorporation and bylaws of Parent, shall be as set forth in Section 5.11; and

(e) the directors and officers of the Surviving Corporation, each to hold office in accordance with the certificate of incorporation and bylaws of the Surviving Corporation, shall be the directors and officers of Parent as set forth in Section 5.11, after giving effect to the provisions of Section 5.11, or such other persons as shall be mutually agreed upon by Parent and the Company.

1.5 **Conversion of Shares**.

(a) At the Effective Time, by virtue of the Merger and without any further action on the part of Parent, Merger Sub, the Company or any stockholder of the Company or Parent:

(i) any shares of Company Capital Stock held as treasury stock or held or owned by the Company or Merger Sub immediately prior to the Effective Time shall be canceled and retired and shall cease to exist, and no consideration shall be delivered in exchange therefor; and

(ii) subject to Section 1.5(c) and Section 1.8, each share of Company Capital Stock outstanding immediately prior to the Effective Time (excluding shares to be canceled pursuant to Section 1.5(a)(i) and excluding Dissenting Shares (as defined below)) shall be automatically converted solely into the right to receive a number of shares of Parent Common Stock equal to the amount determined pursuant to the Company Charter Amendment (as defined below) at the applicable Exchange Ratio set forth therein (in the aggregate, the "***Merger Consideration***").

(b) If any shares of Company Capital Stock outstanding immediately prior to the Effective Time are unvested or are subject to a repurchase option or a risk of forfeiture under any applicable restricted stock purchase agreement or other similar agreement with the Company, then the shares of Parent Common Stock issued in exchange for such shares of Company Capital Stock will to the same extent be unvested and subject to the same repurchase option or risk of forfeiture, and such shares of Parent Common Stock shall accordingly be marked with appropriate legends. The Company shall take all actions that may be reasonably necessary to ensure that, from and after the Effective Time, Parent is entitled to exercise any such repurchase option or other right set forth in any such restricted stock purchase agreement or other agreement in accordance with its terms.

(c) No fractional shares of Parent Common Stock shall be issued in connection with the Merger, and no certificates or scrip for any such fractional shares shall be issued. Any holder of Company Capital Stock who would otherwise be entitled to receive a fraction of a share of Parent Common Stock (after aggregating all fractional shares of Parent Common Stock issuable to such holder) shall, in lieu of such fraction of a share and upon surrender by such holder of a letter of transmittal in accordance with Section 1.7 and any accompanying documents as required therein, be paid in cash the dollar amount (rounded to the nearest whole cent), without interest, determined by multiplying such fraction by the Parent Closing Price.

(d) All Company Options outstanding immediately prior to the Effective Time under the Company Plans shall be treated in accordance with Section 5.4.

(e) Each share of common stock, $0.0001 par value per share, of Merger Sub issued and outstanding immediately prior to the Effective Time shall be converted into and exchanged for one validly issued, fully paid and nonassessable share of common stock, $0.0001 par value per share, of the Surviving Corporation. Each stock certificate of Merger Sub evidencing ownership of any such shares shall, as of the Effective Time, evidence ownership of such shares of common stock of the Surviving Corporation.

1.6 **Closing of the Company's Transfer Books**. At the Effective Time: (a) all shares of Company Capital Stock outstanding immediately prior to the Effective Time shall be treated in accordance with Section 1.5(a), and all holders of certificates representing shares of Company Capital Stock that were outstanding immediately prior to the Effective Time shall cease to have any rights as stockholders of the Company; and (b) the stock transfer books of the Company shall be closed with respect to all shares of Company Capital Stock outstanding immediately prior to the Effective Time. No further transfer of any such shares of Company Capital Stock shall be made on such stock transfer books after the Effective Time. If, after the Effective Time, a valid certificate previously representing any shares of Company Capital Stock outstanding immediately prior to the Effective Time (a "***Company Stock Certificate***") is presented to the Exchange Agent or to the Surviving Corporation, such Company Stock Certificate shall be canceled and shall be exchanged as provided in Sections 1.5 and 1.7.

1.7 **Surrender of Certificates**.

(a) On or prior to the Closing Date, Parent and the Company shall agree upon and select a reputable bank, transfer agent or trust company to act as exchange agent in the Merger (the "***Exchange Agent***"). At the Effective Time, Parent shall deposit with the Exchange Agent: (i) certificates or evidence of book-entry shares representing the Parent Common Stock issuable pursuant to Section 1.5(a) and (ii) cash sufficient

to make payments in lieu of fractional shares in accordance with Section 1.5(c). The Parent Common Stock and cash amounts so deposited with the Exchange Agent, together with any dividends or distributions received by the Exchange Agent with respect to such shares, are referred to collectively as the "***Exchange Fund.***"

(b) Promptly after the Effective Time, the Parties shall cause the Exchange Agent to mail to the Persons who were record holders of shares of Company Capital Stock that were converted into the right to receive the Merger Consideration: (i) a letter of transmittal in customary form and containing such provisions as Parent may reasonably specify (including a provision confirming that delivery of Company Stock Certificates shall be effected, and risk of loss and title to Company Stock Certificates shall pass, only upon proper delivery of such Company Stock Certificates to the Exchange Agent); and (ii) instructions for effecting the surrender of Company Stock Certificates in exchange for shares of Parent Common Stock. Upon surrender of a Company Stock Certificate to the Exchange Agent for exchange, together with a duly executed letter of transmittal and such other documents as may be reasonably required by the Exchange Agent or Parent: (A) the holder of such Company Stock Certificate shall be entitled to receive in exchange therefor a certificate or certificates or book-entry shares representing the Merger Consideration (in a number of whole shares of Parent Common Stock) that such holder has the right to receive pursuant to the provisions of Section 1.5(a) (and cash in lieu of any fractional share of Parent Common Stock, pursuant to the provisions of Section 1.5(c)); and (B) the Company Stock Certificate so surrendered shall be canceled. Until surrendered as contemplated by this Section 1.7(b), each Company Stock Certificate shall be deemed, from and after the Effective Time, to represent only the right to receive a certificate or certificates or book-entry shares of Parent Common Stock, representing the Merger Consideration (and cash in lieu of any fractional share of Parent Common Stock). If any Company Stock Certificate shall have been lost, stolen or destroyed, Parent may, in its discretion and as a condition precedent to the delivery of any shares of Parent Common Stock, require the owner of such lost, stolen or destroyed Company Stock Certificate to provide an applicable affidavit with respect to such Company Stock Certificate and post a bond indemnifying Parent against any claim suffered by Parent related to the lost, stolen or destroyed Company Stock Certificate as Parent may reasonably request. In the event of a transfer of ownership of a Company Stock Certificate that is not registered in the transfer records of the Company, payment of the Merger Consideration in respect of such Company Stock Certificate may be made to a Person other than the Person in whose name such Company Stock Certificate so surrendered is registered if such Company Stock Certificate shall be properly endorsed or otherwise be in proper form for transfer and the Person requesting such payment shall pay any transfer or other Taxes required by reason of the transfer or establish to the reasonable satisfaction of Parent that such Taxes have been paid or are not applicable. The Merger Consideration and any dividends or other distributions as are payable pursuant to Section 1.7(c) shall be deemed to have been in full satisfaction of any and all rights pertaining to Company Capital Stock formerly represented by such Company Stock Certificates.

(c) No dividends or other distributions declared or made with respect to Parent Common Stock with a record date on or after the Effective Time shall be paid to the holder of any unsurrendered Company Stock Certificate with respect to the shares of Parent Common Stock that such holder has the right to receive in the Merger until such holder surrenders such Company Stock Certificate or provides an affidavit of loss or destruction in lieu thereof in accordance with this Section 1.7 (at which time (or, if later, on the applicable payment date) such holder shall be entitled, subject to the effect of applicable abandoned property, escheat or similar Laws, to receive all such dividends and distributions, without interest).

(d) Any portion of the Exchange Fund that remains undistributed to holders of Company Stock Certificates as of the date that is one year after the Closing Date shall be delivered to Parent upon demand, and any holders of Company Stock Certificates who have not theretofore surrendered their Company Stock Certificates in accordance with this Section 1.7 shall thereafter look only to Parent for satisfaction of their claims for Parent Common Stock, cash in lieu of fractional shares of Parent Common Stock, and any dividends or distributions with respect to shares of Parent Common Stock.

(e) No Party shall be liable to any holder of any Company Stock Certificate or to any other Person with respect to any shares of Parent Common Stock (or dividends or distributions with respect thereto) or for any cash amounts delivered to any public official pursuant to any applicable abandoned property Law, escheat Law or similar Law.

1.8 **Appraisal Rights**.

(a) Notwithstanding any provision of this Agreement to the contrary, shares of Company Capital Stock that are outstanding immediately prior to the Effective Time and which are held by stockholders who have exercised and perfected appraisal rights for such shares of Company Capital Stock in accordance with the DGCL (collectively, the "Dissenting Shares") shall not be converted into or represent the right to receive the Merger Consideration described in Section 1.5 attributable to such Dissenting Shares. Such stockholders shall be entitled to receive payment of the appraised value of such shares of Company Capital Stock held by them in accordance with the DGCL, unless and until such stockholders fail to perfect or effectively withdraw or otherwise lose their appraisal rights under the DGCL. All Dissenting Shares held by stockholders who shall have failed to perfect or shall have effectively withdrawn or lost their right to appraisal of such shares of Company Capital Stock under the DGCL (whether occurring before, at or after the Effective Time) shall thereupon be deemed to be converted into and to have become exchangeable for, as of the Effective Time, the right to receive the Merger Consideration, without interest, attributable to such Dissenting Shares upon their surrender in the manner provided in Sections 1.5 and 1.7.

(b) The Company shall give Parent prompt written notice of any demands by dissenting stockholders received by the Company, withdrawals of such demands and any other instruments served on the Company and any material correspondence received by the Company in connection with such demands, and Parent shall have the right to direct all negotiations and proceedings with respect to such demands; *provided* that the Company shall have the right to participate in such negotiations and proceedings. The Company shall not, except with the prior written consent of Parent, voluntarily make any payment with respect to, or settle or offer to settle, any such demands, or approve any withdrawal of any such demands or agree to do any of the foregoing.

1.9 **Further Action**. If, at any time after the Effective Time, any further action is determined by the Surviving Corporation to be necessary or desirable to carry out the purposes of this Agreement or to vest the Surviving Corporation with full right, title and possession of and to all rights and property of the Company, then the officers and directors of the Surviving Corporation shall be fully authorized, and shall use their and its commercially reasonable efforts (in the name of the Company, in the name of Merger Sub, in the name of the Surviving Corporation and otherwise) to take such action.

1.10 **Withholding**. The Parties and the Exchange Agent shall be entitled to deduct and withhold from the consideration otherwise payable pursuant to this Agreement to any holder of Company Capital Stock or any other Person such amounts as such Party or the Exchange Agent is required to deduct and withhold under the Code or any other Law with respect to the making of such payment. To the extent that amounts are so deducted and withheld and paid to the appropriate Person, such deducted and withheld amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of whom such deduction and withholding was made.

Section 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Subject to Section 10.13(h), except as set forth in the disclosure schedule delivered by the Company to Parent (the "***Company Disclosure Schedule***"), the Company represents and warrants to Parent and Merger Sub as follows:

2.1 **Due Organization; No Subsidiaries**.

(a) The Company is a corporation duly incorporated, validly existing and in good standing under the Laws of Delaware and has all necessary corporate power and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used; and (iii) to perform its obligations under all Contracts by which it is bound.

(b) The Company is duly licensed and qualified to do business, and is in good standing (to the extent applicable in such jurisdiction), under the Laws of all jurisdictions where the nature of its business requires such licensing or qualification other than in jurisdictions where the failure to be so qualified individually or in the aggregate would not be reasonably expected to have a Company Material Adverse Effect.

(c) The Company does not have and has never had any Subsidiaries.

(d) The Company is not and has not been, directly or indirectly, a party to, member of or participant in any partnership, joint venture or similar business Entity. The Company has not agreed to make, is not obligated to make, and is not bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other Entity. The Company has not, at any time, been a general partner of, or has otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other Entity

2.2 **Organizational Documents**. The Company has made available to Parent accurate and complete copies of the Organizational Documents of the Company in effect as of the date of this Agreement. The Company is not in breach or violation of its Organizational Documents.

2.3 **Authority; Binding Nature of Agreement**.

(a) The Company has all necessary corporate power and authority to enter into and to perform its obligations under this Agreement and, subject to receipt of the Required Company Stockholder Vote, to perform its obligations hereunder and to consummate the Contemplated Transactions. The Company Board (at meetings duly called and held) has (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of the Company and its stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of the Company vote in favor of the Company Stockholder Matters.

(b) This Agreement has been duly executed and delivered by the Company and assuming the due authorization, execution and delivery by Parent and Merger Sub, constitutes the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, subject to the Enforceability Exceptions. The Company Board has approved the Contemplated Transactions.

2.4 **Vote Required**. The affirmative vote (or written consent) of (a) the holders of a majority of the shares of Company Common Stock and Company Preferred Stock, voting as a single class, and (b) the holders of a majority of the shares of Company Preferred Stock, voting together as a single class, (c) the holders of at least thirty two point three percent (32.3%) of the outstanding shares of Series B Preferred Stock, voting together as a single class, in each case, outstanding on the record date for the written consent in lieu of a meeting pursuant to Section 228 of the DGCL approving the Company Stockholder Matters, in a form reasonably acceptable to Parent (collectively, the "Company Stockholder Written Consent") and entitled to vote thereon (collectively, the "***Required Company Stockholder Vote***"), is the only vote (or written consent) of the holders of any class or series of Company Capital Stock necessary to adopt and approve the Company Stockholder Matters.

2.5 **Non-Contravention; Consents**. Subject to obtaining the Required Company Stockholder Vote and the filing of the Certificate of Merger required by the DGCL, neither (x) the execution, delivery or performance of this Agreement by the Company, nor (y) the consummation of the Contemplated Transactions, will directly or indirectly (with or without notice or lapse of time):

(a) contravene, conflict with or result in a violation of any of the provisions of the Company's Organizational Documents;

(b) contravene, conflict with or result in a material violation of, or to the Knowledge of the Company give any Governmental Body or other Person the right to challenge the Contemplated Transactions or to exercise any material remedy or obtain any material relief under, any Law or any order, writ, injunction, judgment or decree to which the Company, or any of the assets owned or used by the Company, is subject, except as would not reasonably be expected to be material to the Company or its business;

(c) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Body the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by the Company, except as would not reasonably be expected to be material to the Company or its business;

(d) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Company Material Contract, or give any Person the right to: (i) declare a default or exercise any remedy under any Company Material Contract; (ii) any material payment, rebate, chargeback,

penalty or change in delivery schedule under any Company Material Contract; (iii) accelerate the maturity or performance of any Company Material Contract; or (iv) cancel, terminate or modify any term of any Company Material Contract, except in the case of any non-material breach, default, penalty or modification; or

(e) result in the imposition or creation of any Encumbrance upon or with respect to any asset owned or used by the Company (except for Permitted Encumbrances).

Except for (i) any Consent set forth on Section 2.5 of the Company Disclosure Schedule under any Company Contract, (ii) the Required Company Stockholder Vote, (iii) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware pursuant to the DGCL, and (iv) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities Laws, the Company is not and will not be required to make any filing with or give any notice to, or to obtain any Consent from, any Person in connection with (A) the execution, delivery or performance of this Agreement and the Company Lock-Up Agreements or (B) the consummation of the Contemplated Transactions, which if individually or in the aggregate were not given or obtained, would reasonably be expected to prevent or materially delay the ability of Parent and Merger Sub to consummate the Contemplated Transactions. The Company Board has taken and will take all actions necessary to ensure that the restrictions applicable to business combinations contained in Section 203 of the DGCL are, and will be, inapplicable to the execution, delivery and performance of this Agreement, the Company Lock-Up Agreements and to the consummation of the Contemplated Transactions. No other state takeover statute or similar Law applies or purports to apply to the Merger, this Agreement, the Company Lock-Up Agreements or any of the Contemplated Transactions.

2.6 **Capitalization**.

(a) The authorized Company Capital Stock as of the date of this Agreement consists of (i) 36,000,000 shares of Company Common Stock, par value $0.0001 per share, of which 8,933,537 shares have been issued and are outstanding as of the date of this Agreement and of which 1,350,000 shares are held by the Company as treasury shares as of the date of this Agreement, and (ii) 21,170,801 shares of preferred stock, par value $0.0001 per share (the "***Company Preferred Stock***"), of which 21,170,801 have been issued and are outstanding as of the date of this Agreement, consisting of 11,204,513 shares of Series A Preferred Stock and 9,966,288 shares of Series B Preferred Stock. Section 2.6(a) of the Company Disclosure Schedule lists, as of the date of this Agreement each record holder of issued and outstanding Company Capital Stock and the number and type of shares of Company Capital Stock held by such holder.

(b) All of the outstanding shares of Company Common Stock and Company Preferred Stock have been duly authorized and validly issued, and are fully paid and nonassessable. Except as set forth in the Company Bylaws or Investor Agreements, none of the outstanding shares of Company Capital Stock is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Company Capital Stock is subject to any right of first refusal in favor of the Company. Except as contemplated herein and in the Company Bylaws and Investor Agreements, there is no Company Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Company Capital Stock. The Company is not under any obligation, nor is it bound by any Contract pursuant to which it may become obligated, to repurchase, redeem or otherwise acquire any outstanding shares of Company Capital Stock or other securities. Section 2.6(b) of the Company Disclosure Schedule accurately and completely lists all repurchase or forfeiture rights held by the Company with respect to shares of Company Capital Stock (including shares issued pursuant to the exercise of stock options) and specifies which of those repurchase rights are currently exercisable and whether the holder of such shares of Company Capital Stock timely filed an election with the relevant Governmental Bodies under Section 83(b) of the Code with respect to such shares.

(c) Except for the Company Plans (and awards granted thereunder), the Company does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. As of the date of this Agreement, the Company has reserved 3,711,490 shares of Company Common Stock for issuance under the Company Plans, of which 283,537 shares have been issued and are currently outstanding, 2,229,990 shares have been reserved for issuance upon exercise of

Company Options previously granted and currently outstanding under the Company Plans, and 1,197,963 shares of Company Common Stock remain available for future issuance pursuant to the Company Plans. Only shares of Company Common Stock are subject to Company Options. Section 2.6(c) of the Company Disclosure Schedule sets forth the following information with respect to each Company Option outstanding as of the date of this Agreement: (i) the name of the optionee; (ii) the number of shares of Company Common Stock subject to such Company Option at the time of grant; (iii) the number of shares of Company Common Stock subject to such Company Option as of the date of this Agreement; (iv) the exercise price of such Company Option; (v) the date on which such Company Option was granted; (vi) the applicable vesting schedule, including the number of vested and unvested shares as of the date of this Agreement and any acceleration provisions; (vii) the date on which such Company Option expires; and (viii) whether such Company Option is intended to constitute an "incentive stock option" (as defined in the Code) or a non-qualified stock option. The Company has made available to Parent accurate and complete copies of the Company Plans and all forms of stock option and other award agreements evidencing outstanding options granted thereunder. No vesting of Company Options will accelerate in connection with the closing of the Contemplated Transactions.

(d) Except for the Company Options set forth on Section 2.6(c) of the Company Disclosure Schedule, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of the Company; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of the Company; or (iii) condition or circumstance that is reasonably likely to give rise to or provide a basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive any shares of capital stock or other securities of the Company. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to the Company.

(e) All outstanding shares of Company Common Stock, Company Preferred Stock, Company Options, and other securities of the Company have been issued and granted in material compliance with (i) all applicable securities Laws and other applicable Law and (ii) all requirements set forth in applicable Contracts.

2.7 **Financial Statements**.

(a) Concurrently with the execution hereof, the Company has provided to Parent true and complete copies of (i) the Company's audited balance sheets at December 31, 2018 and 2017 together with related audited statements of income, stockholders' equity and cash flows, and notes thereto, of the Company for the fiscal years then ended and (ii) the Company Unaudited Interim Balance Sheet, together with the unaudited statements of income, stockholders' equity and cash flows of the Company for the period reflected in the Company Unaudited Interim Balance Sheet (collectively, the "***Company Financials***"). The Company Financials were prepared in accordance with GAAP (except as may be indicated in the notes to such financial statements and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments) and fairly present, in all material respects, the financial position and operating results of the Company as of the dates and for the periods indicated therein.

(b) The Company maintains books and records reflecting its assets and liabilities and maintains a system of internal accounting controls designed to provide reasonable assurance: (i) that transactions are executed in accordance with management's general or specific authorizations; (ii) that transactions are recorded as necessary to permit preparation of the financial statements of the Company in accordance with GAAP; and (iii) regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements of the Company. The Company maintains internal control over financial reporting that provides reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes.

(c) Section 2.7(c) of the Company Disclosure Schedule lists, and the Company has delivered to Parent accurate and complete copies of the documentation creating or governing, all securitization transactions and "off-balance sheet arrangements" (as defined in Item 303(c) of Regulation S-K under the Exchange Act) effected by the Company since January 1, 2017.

(d) There have been no formal internal investigations regarding financial reporting or accounting policies and practices discussed with, reviewed by or initiated at the direction of the chief executive officer, chief financial officer or general counsel of the Company, the Company Board or any committee thereof. Neither the Company nor its independent auditors have identified (i) any significant deficiency or material weakness in the design or operation of the system of internal accounting controls utilized by the Company, (ii) any fraud, whether or not material, that involves the Company, the Company's management or other employees who have a role in the preparation of financial statements or the internal accounting controls utilized by the Company or (iii) any claim or allegation regarding any of the foregoing.

2.8 **Absence of Changes**. Since the date of the Company Unaudited Interim Balance Sheet, the Company has conducted its business only in the Ordinary Course of Business (except for the execution and performance of this Agreement and the discussions, negotiations and transactions related thereto) and there has not been any (a) Company Material Adverse Effect or (b) action, event or occurrence that would have required consent of Parent pursuant to Section 4.2(b) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

2.9 **Absence of Undisclosed Liabilities**. As of the date hereof, the Company does not have any liability, indebtedness, obligation or expense of any kind, whether accrued, absolute, contingent, matured or unmatured (whether or not required to be reflected in the financial statements in accordance with GAAP) (each a "***Liability***"), individually or in the aggregate, of a type required to be recorded or reflected on a balance sheet or disclosed in the footnotes thereto under GAAP, except for: (a) Liabilities disclosed, reflected or reserved against in the Company Unaudited Interim Balance Sheet; (b) Liabilities that have been incurred by the Company since the date of the Company Unaudited Interim Balance Sheet in the Ordinary Course of Business; (c) Liabilities for performance of obligations of the Company under Company Contracts; (d) Liabilities incurred in connection with the Contemplated Transactions; (e) Liabilities which would not, individually or in the aggregate, reasonably be expected to be material to the Company; and (f) Liabilities described in Section 2.9 of the Company Disclosure Schedule.

2.10 **Title to Assets**. The Company owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all tangible properties or tangible assets and equipment used or held for use in its business or operations or purported to be owned by it that are material to the Company or its business, including: (a) all tangible assets reflected on the Company Unaudited Interim Balance Sheet; and (b) all other tangible assets reflected in the books and records of the Company as being owned by the Company. All of such assets are owned or, in the case of leased assets, leased by the Company free and clear of any Encumbrances, other than Permitted Encumbrances.

2.11 **Real Property; Leasehold**. The Company does not own and has never owned any real property. The Company has made available to Parent: (a) an accurate and complete list of all real properties with respect to which the Company directly or indirectly holds a valid leasehold interest as well as any other real estate that is in the possession of or leased by the Company, and (b) copies of all leases under which any such real property is possessed (the "***Company Real Estate Leases***"), each of which is in full force and effect, with no existing material default thereunder. The Company's use and operation of each such leased property conforms to all applicable Laws in all material respects, and the Company has exclusive possession of each such leased property and has not granted any occupancy rights to tenants or licensees with respect to such leased property. In addition, each such leased property is free and clear of all Encumbrances other than Permitted Encumbrances.

2.12 **Intellectual Property.**

(a) Section 2.12(a) of the Company Disclosure Schedule identifies each item of material Company IP that is the subject of a registration or application in any jurisdiction ("***Company Registered IP***"), including, with respect to each patent and patent application: (i) the name of the applicant/registrant, (ii) the jurisdiction of application/registration, (iii) the application or registration number and (iv) any other co-owners. To the Knowledge of the Company, each of the patents and patent applications included in Section 2.12(a) of the Company Disclosure Schedule properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States. To the Knowledge of the Company, as of the date of this Agreement, no cancellation, interference, opposition, reissue, reexamination or other proceeding of any nature (other than office actions or similar communications issued by any Governmental Body in the ordinary course of prosecution of any pending

applications for registration) is pending or threatened in writing, in which the scope, validity, enforceability or ownership of any Company IP is being or has been contested or challenged. To the Knowledge of the Company, each item of Company IP is valid and enforceable, and with respect to Company Registered IP, subsisting. Except as set forth in Section 2.12(a) of the Company Disclosure Schedule, there are no actions that must be taken within ninety (90) days of the Closing, the failure of which will result in the abandonment, lapse or cancellation of any Company Registered IP.

(b) Except as has not had and would not reasonably be expected to have, individually or in the aggregate, a Company Material Adverse Effect, the Company exclusively owns, is the sole assignee of, or has exclusively licensed all material Company IP (other than as disclosed on Section 2.12(b) of the Company Disclosure Schedule), free and clear of all Encumbrances other than Permitted Encumbrances. The Company IP and the Intellectual Property Rights licensed to the Company pursuant to a valid, enforceable written agreement constitute all Intellectual Property Rights used in, material to or otherwise necessary for the operation of the Company's business as currently conducted. To the Knowledge of the Company, each Company Associate involved in the creation or development of any material Company IP, pursuant to such Company Associate's activities on behalf of the Company, has signed a valid and enforceable written agreement containing an assignment of such Company Associate's rights in such Company IP to the Company. Each Company Associate who has or has had access to the Company's trade secrets or confidential information has signed a valid and enforceable written agreement containing confidentiality provisions protecting the Company IP, trade secrets and confidential information. The Company has taken commercially reasonable steps to protect and preserve the confidentiality of its trade secrets and confidential information.

(c) To the Knowledge of the Company, no funding, facilities or personnel of any Governmental Body or any university, college, research institute or other educational institution has been used to create Company IP, except for any such funding or use of facilities or personnel that does not result in such Governmental Body or institution obtaining ownership rights or a license to such Company IP or the right to receive royalties for the practice of such Company IP.

(d) Section 2.12(d) of the Company Disclosure Schedule sets forth each license agreement pursuant to which the Company (i) is granted a license under any material Intellectual Property Right owned by any third party that is used by the Company in its business as currently conducted (each a "***Company In-bound License***") or (ii) grants to any third party a license under any material Company IP or material Intellectual Property Right licensed to the Company under a Company In-bound License (each a "***Company Out-bound License***") (*provided*, that, Company In-bound Licenses shall not include, when entered into in the Ordinary Course of Business, material transfer agreements, clinical trial agreements, agreements with Company Associates, services agreements, commercially available Software-as-a-Service offerings or off-the-shelf software licenses; and Company Out-bound Licenses shall not include, when entered into in the Ordinary Course of Business, material transfer agreements, clinical trial agreements, services agreements, or non-exclusive outbound licenses). All Company In-bound Licenses and Company Out-bound Licenses are in full force and effect and are valid, enforceable and binding obligations of the Company and, to the Knowledge of Company, each other party to such Company In-bound Licenses or Company Out-bound Licenses. Neither the Company, nor to the Knowledge of the Company, any other party to such Company In-bound Licenses or Company Out-bound Licenses, is in material breach under any Company In-bound Licenses or Company Out-bound Licenses.

(e) To the Knowledge of the Company: (i) the operation of the businesses of the Company as currently conducted does not infringe, misappropriate or otherwise violate any Intellectual Property Rights of any other Person and (ii) no other Person is infringing, misappropriating or otherwise violating any Company IP. No Legal Proceeding is pending (or, to the Knowledge of the Company, is threatened in writing) (A) against the Company alleging that the operation of the businesses of the Company infringes or constitutes the misappropriation or other violation of any Intellectual Property Rights of another Person or (B) by the Company alleging that another Person has infringed, misappropriated or otherwise violated any of the Company IP or any Intellectual Property Rights exclusively licensed to the Company. Since January 1, 2016, the Company has not received any written notice or other written communication alleging that the operation of the business of the Company infringes or constitutes the misappropriation or other violation of any Intellectual Property Right of another Person.

(f) None of the Company IP or, to the Knowledge of the Company, any material Intellectual Property Rights exclusively licensed to the Company is subject to any pending or outstanding injunction, directive, order, judgment or other disposition of dispute that adversely and materially restricts the use, transfer, registration or licensing by the Company of any such Company IP or material Intellectual Property Rights exclusively licensed to the Company.

(g) To the Knowledge of the Company, the Company and the operation of the Company's business are in substantial compliance with all Laws pertaining to data privacy and data security of any personally identifiable information and sensitive business information (collectively, "***Sensitive Data***") except to the extent that such noncompliance has not and would not reasonably be expected to have a Company Material Adverse Effect. To the Knowledge of the Company, since January 1, 2016, there have been (i) no material losses or thefts of data or security breaches relating to Sensitive Data used in the business of the Company, (ii) no violations of any security policy of the Company regarding any such Sensitive Data used in the business of the Company and (iii) no unauthorized access, unauthorized use or unintended or improper disclosure of any Sensitive Data used in the business of the Company, in each case of (i) through (iii), except as would not reasonably be expected to, individually or in the aggregate, have a Company Material Adverse Effect. The Company has taken commercially reasonable steps and implemented reasonable disaster recovery and security plans and procedures to protect the information technology systems used in, material to or necessary for operation of the Company's business as currently conducted from unauthorized use or access. To the Knowledge of the Company, there have been no material malfunctions or unauthorized intrusions or breaches of the information technology systems used in, material to or necessary for the operation of the Company's business as currently conducted.

2.13 **Agreements, Contracts and Commitments**.

(a) Section 2.13(a) of the Company Disclosure Schedule lists the following Company Contracts in effect as of the date of this Agreement (and, except with respect to clauses (xii) and (xiii) below, other than any Benefit Plans) (each, a "***Company Material Contract***" and collectively, the "***Company Material Contracts***"):

(i) each Company Contract relating to any agreement of indemnification or guaranty not entered into in the Ordinary Course of Business;

(ii) each Company Contract containing (A) any covenant limiting the freedom of the Company or the Surviving Corporation to engage in any line of business or compete with any Person, (B) any most-favored pricing arrangement, (C) any exclusivity provision or (D) any non-solicitation provision, in each case, except for restrictions that would not materially affect the ability of the Company to conduct its business;

(iii) each Company Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of $75,000 pursuant to its express terms and not cancelable without penalty;

(iv) each Company Contract relating to the disposition or acquisition of material assets or any ownership interest in any Entity, in each case, involving payments in excess of $75,000, other than Company Contracts in which the applicable acquisition or disposition has been consummated and there are no material ongoing obligations;

(v) each Company Contract relating to any mortgages, indentures, loans, notes or credit agreements, security agreements or other agreements or instruments relating to the borrowing of money or extension of credit or creating any material Encumbrances with respect to any assets of the Company or any loans or debt obligations with officers or directors of the Company;

(vi) each Company Contract requiring payment by or to the Company after the date of this Agreement in excess of $75,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of the Company; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, development or other agreement currently in force under which the Company has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to

which the Company has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by the Company; or (D) any Company Contract with any third party providing any services relating to the manufacture or production of any product, service or technology of the Company or any Contract to sell, distribute or commercialize any products or service of the Company;

(vii) each Company Contract with any financial advisor, broker, finder, investment banker or other similar Person, providing advisory services to the Company in connection with the Contemplated Transactions;

(viii) each Company Real Estate Lease;

(ix) each Company Contract with any Governmental Body (other than clinical trial agreements for clinical trial studies, cooperative research and development agreements and confidentiality agreements);

(x) each Company Out-bound License and Company In-bound License, and each Company Contract containing a covenant not to sue or otherwise enforce any Intellectual Property Rights;

(xi) each Company Contract containing any royalty, dividend or similar arrangement based on the revenues or profits of the Company;

(xii) each (A) Company Contract, offer letter, employment agreement or other agreement with any employee, (1) is not immediately terminable at will by the Company without advance notice, severance, or other cost or liability or (2) provides for retention payments, change of control payments, severance, accelerated vesting or any payment or benefit that may or will become due as a result of the Merger (whether alone or in connection with any other event) and (B) each Company Contract, independent contractor agreement, or other agreement with any consultant or service provider that (1) is not immediately terminable at will by the Company without more than 30 days' prior notice, severance, or other cost or liability or (2) provides for retention payments, change of control payments, severance, accelerated vesting or any payment or benefit that may or will become due as a result of the Merger (whether alone or in connection with any other event);

(xiii) each Company Contract providing any option to receive a license or other right, any right of first negotiation, any right of first refusal or any similar right to any Person related to any material Company IP or material Intellectual Property Right licensed to the Company under a Company In-bound License;

(xiv) each Company Contract entered into in settlement of any legal proceeding or other dispute; or

(xv) any other Company Contract that is not terminable at will (with no penalty or payment) by the Company, and (A) which involves payment or receipt by the Company after the date of this Agreement under any such agreement, Contract or commitment of more than $75,000 in the aggregate, or obligations after the date of this Agreement in excess of $75,000 in the aggregate or (B) that is material to the business or operations of the Company.

(b) The Company has delivered or made available to Parent complete copies of all Company Material Contracts, including all amendments thereto. There are no Company Material Contracts that are not in written form. The Company has not, nor to the Company's Knowledge, as of the date of this Agreement has any other party to a Company Material Contract, breached, violated or defaulted under, or received notice that it breached, violated or defaulted under, any of the terms or conditions of any Company Material Contract in such manner as would permit any other party to cancel or terminate any such Company Material Contract, or would permit any other party to seek damages which would reasonably be expected to be material to the Company or its business. As to the Company, as of the date of this Agreement, each Company Material Contract is valid, binding, enforceable and in full force and effect, subject to the Enforceability Exceptions. No Person is renegotiating, or has a right pursuant to the terms of any Company Material Contract to change, any material amount paid or payable to the Company under any Company Material Contract or any other material term or provision of any Company Material Contract.

2.14 **Compliance; Permits; Restrictions.**

(a) The Company is, and since January 1, 2016, has been, in compliance in all material respects with all applicable Laws, including the Federal Food, Drug, and Cosmetic Act ("***FDCA***"), the Food and Drug Administration ("FDA") regulations adopted thereunder, the Public Health Service Act ("***PHSA***") and its implementing regulations and any other similar Law administered or promulgated by the FDA or other comparable Governmental Body responsible for regulation of the development, clinical testing, manufacturing, sale, marketing, distribution and importation or exportation of drug and biopharmaceutical products (each, a "***Drug Regulatory Agency***"), except for any noncompliance, either individually or in the aggregate, which would not be material to the Company. To the Knowledge of the Company, no investigation, claim, suit, proceeding, audit or other action by any Governmental Body is pending or threatened against the Company. There is no agreement, judgment, injunction, order or decree binding upon the Company which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of the Company, any acquisition of material property by the Company or the conduct of business by the Company as currently conducted, (ii) is reasonably likely to have an adverse effect on the Company's ability to comply with or perform any covenant or obligation under this Agreement or (iii) is reasonably likely to have the effect of preventing, delaying, making illegal or otherwise interfering with the Contemplated Transactions.

(b) The Company holds all required Governmental Authorizations which are material to the operation of the business of the Company as currently conducted (the "***Company Permits***"). Section 2.14(b) of the Company Disclosure Schedule identifies each Company Permit. The Company is in material compliance with the terms of the Company Permits. No Legal Proceeding is pending or, to the Knowledge of the Company, threatened, which seeks to revoke, limit, suspend, or materially modify any Company Permit. The rights and benefits of each Company Permit will be available to the Surviving Corporation or its Subsidiaries, as applicable, immediately after the Effective Time on terms substantially identical to those enjoyed by the Company as of the date of this Agreement and immediately prior to the Effective Time.

(c) To the Knowledge of the Company, there are no proceedings pending or threatened against the Company with respect to an alleged material violation by the Company of the FDCA, FDA regulations adopted thereunder, the PHSA and its implementing regulations or any other similar Law administered or promulgated by any Drug Regulatory Agency.

(d) The Company holds all required Governmental Authorizations issuable by any Drug Regulatory Agency necessary or material to the conduct of the business of the Company as currently conducted (collectively, the "***Company Regulatory Permits***") and no such Company Regulatory Permit has been (i) revoked, withdrawn, suspended, canceled or terminated or (ii) modified in any adverse manner. The Company is in compliance in all material respects with the Company Regulatory Permits and have not received any written notice or other written communication, or to the Knowledge of the Company, any other communication from any Drug Regulatory Agency regarding (A) any material violation of or failure to comply materially with any term or requirement of any Company Regulatory Permit or (B) any revocation, withdrawal, suspension, cancellation, termination or material modification of any Company Regulatory Permit. The Company has complied in all material respects with the ICH E9 Guidance for Industry: Statistical Principles for Clinical Trials in the management of the clinical data that have been presented by the Company. To the Knowledge of the Company, there are no facts that would be reasonably likely to result in any warning, untitled or notice of violation letter or Form FDA-483 from the FDA.

(e) All clinical, pre-clinical and other studies and tests conducted by or on behalf of, or sponsored by, the Company, or in which the Company or its current products or product candidates have participated, were and, if still pending, are being conducted in all material respects in accordance with standard medical and scientific research procedures and in compliance in all material respects with the applicable regulations of any applicable Drug Regulatory Agency and other applicable Law, as applicable, including the Good Clinical Practice ("GCP") regulations under 21 C.F.R. Parts 50, 54, 56, 58 and 312. No preclinical or clinical trial conducted by or on behalf of the Company has been terminated or suspended prior to completion for safety or non-compliance reasons. Since January 1, 2016, the Company has not received any

notices, correspondence, or other communications from any Drug Regulatory Agency requiring, or to the Knowledge of the Company threatening to initiate, the termination or suspension of any clinical studies conducted by or on behalf of, or sponsored by, the Company or in which the Company or its current products or product candidates have participated.

(f) To the Knowledge of the Company, the Company is not the subject of any pending or threatened investigation in respect of its business or products by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991), or any amendments thereto. To the Knowledge of the Company, neither the Company nor any of its officers, employees or agents have committed any acts, made any statement, or failed to make any statement, in each case in respect of its business or products that would violate the FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy, and any amendments thereto. None of the Company or any of its officers, employees or, to the Knowledge of the Company, agents has been convicted of any crime or engaged in any conduct that could result in a debarment or exclusion under (i) 21 U.S.C. Section 335a or (ii) any similar applicable Law. No debarment or exclusionary claims, actions, proceedings or investigations in respect of their business or products are pending or, to the Knowledge of the Company, threatened against the Company or any of its officers, employees or, to the Knowledge of the Company, agents.

(g) Neither Company, nor any of its officers, directors, employees or agents has been, is, or is in anticipation of being (based on a conviction by the courts or a finding of fault by a regulatory authority): (a) debarred pursuant to the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335a), as amended from time to time; (b) disqualified from participating in clinical trials pursuant to 21 C.F.R. §312.70, as amended from time to time; (c) disqualified as a testing facility under 21 C.F.R. Part 58, Subpart K, as amended from time to time; (d) excluded, debarred or suspended from or otherwise ineligible to participate in a "Federal Health Care Program" as defined in 42 U.S.C. 1320a-7b(f), as amended from time to time, or any other governmental payment, procurement or non-procurement program; or (e) included on the HHS/OIG List of Excluded Individuals/Entities, the General Services Administration's List of Parties Excluded from Federal Programs, or the FDA Debarment List. Company is not using, nor has it ever used, in any capacity any Person that has ever been, is currently, or to the Knowledge of Company is the subject of a proceeding that could lead to the Company or its officers, directors, employees or agents becoming, as applicable, a Debarred Entity, a Debarred Individual, an Excluded Entity, an Excluded Individual, or a Convicted Entity or a Convicted Individual, nor are they listed on the FDA's Disqualified/Restricted List. The Company, nor any of its officers, directors, employees or agents, has been excluded or threatened with exclusion under state or federal statutes or regulations, including under 42 U.S.C. § 1320a-7 or relevant regulations in 42 C.F.R. Part 1001, or assessed or threatened with assessment of civil money penalties pursuant to 42 C.F.R. Part 1003. Neither the Company nor to its knowledge its officers, directors, employees or agents has taken any action that would now or in the future constitute an improper inducement under federal or state healthcare laws.

(h) The Company is not a Covered Entity under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations promulgated thereunder, all as amended from time to time (collectively "HIPAA"), but the Company has complied in all material respects with all Laws relating to patient, medical or individual health information, if required, including (to the extent applicable) the standards for the privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164, Subparts A and E, the standards for the protection of Electronic Protected Health Information set forth at 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subpart A and Subpart C, the standards for transactions and code sets used in electronic transactions at 45 C.F.R. Part 160, Subpart A and Part 162, and the standards for Breach Notification for Unsecured Protected Health Information at 45 C.F.R. Part 164, Subpart D, all as amended from time to time. The Company has entered into, where required, and is in compliance in all material respects with the terms of all Business Associate (as defined in HIPAA) agreements ("***Business Associate Agreements***") to which the Company is a party or otherwise bound. To the extent applicable, the Company has created and maintained written policies and procedures to protect the privacy of all protected health information, provides training to all employees and agents as required under HIPAA, and has implemented security procedures, including physical, technical and administrative safeguards, to protect all personal information and Protected Health Information stored or transmitted in electronic form. The Company has not received written notice from the Office for Civil Rights for the U.S. Department of Health

and Human Services or any other Governmental Body of any allegation regarding its failure to comply with HIPAA or any other state law or regulation applicable to the protection of individually identifiable health information or personally identifiable information. No successful Security Incident, Breach of Unsecured Protected Health Information or breach of personally identifiable information under applicable state or federal laws have occurred with respect to information maintained or transmitted to the Company or an agent or third party subject to a Business Associate Agreement with the Company. If required, the Company is currently submitting, receiving and handling or is capable of submitting receiving and handling transactions in accordance with the Standard Transaction Rule. All capitalized terms in this Section 2.14(f) not otherwise defined in this Agreement shall have the meanings set forth under HIPAA.

2.15 **Legal Proceedings; Orders.**

(a) As of the date of this Agreement, to the Knowledge of the Company, there is no material pending Legal Proceeding and no Person has threatened in writing to commence any Legal Proceeding: (i) that involves (A) the Company, (B) any Company Associate (in his or her capacity as such) or (C) any of the material assets owned or used by the Company; or (ii) that challenges, or that would have the effect of preventing, delaying, making illegal or otherwise interfering with, the Contemplated Transactions.

(b) Since January 1, 2016 through the date of this Agreement, no Legal Proceeding has been pending against the Company that resulted in material liability to the Company.

(c) There is no order, writ, injunction, judgment or decree to which the Company, or any of the material assets owned or used by the Company, is subject. To the Knowledge of the Company, no officer of the Company is subject to any order, writ, injunction, judgment or decree that prohibits such officer or employee from engaging in or continuing any conduct, activity or practice relating to the business of the Company or to any material assets owned or used by the Company.

2.16 **Tax Matters.**

(a) The Company has timely filed all income Tax Returns and other material Tax Returns that it was required to file under applicable Law. All such Tax Returns are correct and complete in all material respects and have been prepared in compliance with all applicable Law. No written claim has ever been made by any Governmental Body in any jurisdiction where the Company does not file a particular Tax Return or pay a particular Tax that the Company is subject to taxation by that jurisdiction.

(b) All income and other material Taxes due and owing by the Company on or before the date hereof (whether or not shown on any Tax Return) have been fully paid. The unpaid Taxes of the Company did not, as of the date of the Company Unaudited Interim Balance Sheet, materially exceed the reserve for Tax liability (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax items) set forth on the face of the Company Unaudited Interim Balance Sheet. Since the date of the Company Unaudited Interim Balance Sheet, the Company has not incurred any material Liability for Taxes outside the Ordinary Course of Business.

(c) All Taxes that the Company is or was required by Law to withhold or collect have been duly and timely withheld or collected in all material respects on behalf of its respective employees, independent contractors, stockholders, lenders, customers or other third parties and, have been timely paid to the proper Governmental Body or properly set aside in accounts for this purpose.

(d) There are no Encumbrances for material Taxes (other than Permitted Encumbrances) upon any of the assets of the Company.

(e) No deficiencies for income or other material Taxes with respect to the Company have been claimed, proposed or assessed by any Governmental Body in writing. There are no pending or ongoing, and to the Knowledge of the Company, threatened audits, assessments or other actions for or relating to any liability in respect of a material amount of Taxes of the Company. Neither the Company nor any of its predecessors has waived any statute of limitations in respect of any income or other material Taxes or agreed to any extension of time with respect to any income or other material Tax assessment or deficiency.

(f) The Company has not been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(g) The Company is not a party to any Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, or similar agreement or arrangement, other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes.

(h) The Company will not be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any Tax period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for Tax purposes filed on or prior to the Closing Date; (ii) use of an improper method of accounting for a Tax period ending on or prior to the Closing Date; (iii) "closing agreement" as described in Section 7121 of the Code (or any similar provision of state, local or foreign Law) executed on or prior to the Closing Date; (iv) intercompany transaction or excess loss account described in Treasury Regulations under Section 1502 of the Code (or any similar provision of state, local or foreign Law) entered into on or prior to the Closing Date; (v) installment sale or open transaction disposition made on or prior to the Closing Date; (vi) prepaid amount received on or prior to the Closing Date; or (vii) election under Section 108(i) of the Code (or any similar provision of state, local or foreign Law) made on or prior to the Closing Date. The Company has not made any election under Section 965(h) of the Code.

(i) The Company has never been (i) a member of a consolidated, combined or unitary Tax group (other than such a group the common parent of which is the Company) or (ii) a party to any joint venture, partnership, or other arrangement that is treated as a partnership for U.S. federal income Tax purposes. The Company does not have any Liability for any material Taxes of any Person (other than the Company) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Law), or as a transferee or successor.

(j) The Company has not, since January 1, 2016, distributed stock of another Person, or had its stock distributed by another Person, in a transaction that was purported or intended to be governed in whole or in part by Section 355 of the Code or Section 361 of the Code (or any similar provisions of state, local or foreign Law).

(k) The Company (i) is, and since its formation has been, a domestic corporation for United States federal income tax purposes; and (ii) has never had a permanent establishment (within the meaning of an applicable Tax treaty) or otherwise had an office or fixed place of business in a country other than the United States.

(l) The Company has not participated in or been a party to a transaction that, as of the date of this Agreement, constitutes a "listed transaction" that is required to be reported to the IRS pursuant to Section 6011 of the Code and applicable Treasury Regulations thereunder.

(m) The Company has not taken or agreed to take any action or knows of any fact that would reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment.

For purposes of this Section 2.16, each reference to the Company shall be deemed to include any Person that was liquidated into, merged with, or is otherwise a predecessor to, the Company.

2.17 **Employee and Labor Matters; Benefit Plans.**

(a) Section 2.17(a) of the Company Disclosure Schedule is a list of all Company Benefit Plans, including, without limitation, each Company Benefit Plan that provides for retirement, change in control, stay or retention, deferred compensation, incentive compensation, severance or retiree medical or life insurance benefits. "***Company Benefit Plan***" means each (i) "employee benefit plan" as defined in Section 3(3) of ERISA and (ii) other pension, retirement, deferred compensation, excess benefit, profit sharing, bonus, incentive, equity or equity-based (other than individual Company Options made pursuant to the Company's standard forms, in which case only representative standard forms of such stock option agreements shall be scheduled), phantom equity, employment (other than individual employment agreements made pursuant to the Company's standard forms, in which case only representative standard forms of such employment agreements shall be scheduled), offer letter (other than individual offer letters made pursuant to the Company's standard forms, in which case only representative standard forms of such offers shall be scheduled), consulting, severance, change-of-control, retention, health, life, disability, group insurance, paid-time off, holiday, welfare and fringe benefit plan, program, agreement, contract, or arrangement (whether written or unwritten, qualified or nonqualified, funded or unfunded and including

any that have been frozen), in any case, maintained, contributed to, or required to be contributed to, by the Company or any of its Subsidiaries for the benefit of any current or former employee, director, officer or independent contractor of the Company or under which the Company has any actual or contingent liability (including, without limitation, as to the result of it being treated as a single employer under Code Section 414 with any other person).

(b) As applicable with respect to each Company Benefit Plan, the Company has made available to Parent, true and complete copies of (i) each Company Benefit Plan, including all amendments thereto, and in the case of an unwritten Company Benefit Plan, a written description thereof, (ii) all current trust documents, investment management contracts, custodial agreements, administrative services agreements and insurance and annuity contracts relating thereto, (iii) the current summary plan description and each summary of material modifications thereto, (iv) the most recently filed annual reports with any Governmental Body (*e.g.*, Form 5500 and all schedules thereto), (v) the most recent IRS determination, opinion or advisory letter, (vi) the most recent summary annual reports, nondiscrimination testing reports, actuarial reports, financial statements and trustee reports, (vii) all material records, notices and filings concerning IRS or Department of Labor or other Governmental Body audits or investigations, and (viii) any written reports constituting a valuation of the Company's Capital Stock for purposes of Sections 409A or 422 of the Code, whether prepared internally by the Company or by an outside, third-party valuation firm.

(c) Each Company Benefit Plan has been maintained, operated and administered in compliance in all material respects with its terms and any related documents or agreements and the applicable provisions of ERISA, the Code and all other Laws.

(d) The Company Benefit Plans that are "employee pension benefit plans" within the meaning of Section 3(2) of ERISA and which are intended to meet the qualification requirements of Section 401(a) of the Code have received determination or opinion letters from the IRS on which they may currently rely to the effect that such plans are qualified under Section 401(a) of the Code and the related trusts are exempt from federal income Taxes under Section 501(a) of the Code, respectively, and to the Knowledge of the Company, nothing has occurred that would reasonably be expected to materially adversely affect the qualification of such Company Benefit Plan or the tax exempt status of the related trust.

(e) Neither the Company nor any Company ERISA Affiliate maintains, contributes to, is required to contribute to, or has any actual or contingent liability with respect to, (i) any "employee pension benefit plan" (within the meaning of Section 3(2) of ERISA) that is subject to Title IV or Section 302 of ERISA or Section 412 of the Code, (ii) any "multiemployer plan" (within the meaning of Section 3(37) of ERISA) or (iii) any "multiple employer plan" (within the meaning of Section 413 of the Code). No Company Benefit Plan is a self-funded group health plan that is a "multiple employer welfare arrangement" (within the meaning of Section 3(40) of ERISA).

(f) There are no pending audits or investigations by any Governmental Body involving any Company Benefit Plan, and no pending or, to the Knowledge of the Company, threatened claims (except for individual claims for benefits payable in the normal operation of the Company Benefit Plans), suits or proceedings involving any Company Benefit Plan, any fiduciary thereof or service provider thereto, in any case except as would not be reasonably expected to result in material liability to the Company. All contributions and premium payments required to have been made under any of the Company Benefit Plans or by applicable Law (without regard to any waivers granted under Section 412 of the Code), have been timely made in all material respects and neither the Company nor any Company ERISA Affiliate has any material liability for any unpaid contributions with respect to any Company Benefit Plan.

(g) Neither the Company, any Company ERISA Affiliates, nor to the Knowledge of the Company, any fiduciary, trustee or administrator of any Company Benefit Plan, has engaged in, or in connection with the Contemplated Transactions will engage in, any transaction with respect to any Company Benefit Plan which would subject any such Company Benefit Plan, the Company, or Company ERISA Affiliates or Parent to a material Tax, material penalty or material liability for a "prohibited transaction" under Section 406 of ERISA or Section 4975 of the Code.

(h) No Company Benefit Plan provides death, medical, dental, vision, life insurance or other welfare benefits beyond termination of service or retirement other than coverage mandated by Law and neither the Company nor any Company ERISA Affiliates has made a written or oral representation promising the same.

(i) Neither the execution of, nor the performance of the Contemplated Transactions will either alone or in connection with any other event(s) (i) result in any payment becoming due to any current or former employee, director, officer, or independent contractor of the Company, (ii) increase any amount of compensation or benefits otherwise payable under any Company Benefit Plan, (iii) result in the acceleration of the time of payment, funding or vesting of any benefits under any Company Benefit Plan, (iv) require any contribution or payment to fund any obligation under any Company Benefit Plan or (v) limit the right to merge, amend or terminate any Company Benefit Plan that is subject to ERISA.

(j) Neither the execution of, nor the consummation of, the Contemplated Transactions (either alone or when combined with the occurrence of any other event, including without limitation, a termination of employment) will result in the receipt or retention by any Person who is a "disqualified individual" (within the meaning of Code Section 280G) with respect to the Company of any payment or benefit under any Company Benefit Plan that is or could be characterized as a "parachute payment" (within the meaning of Code Section 280G), determined without regard to the application of Code Section 280G(b)(5).

(k) The exercise price of each Company Option granted to a U.S. taxpayer is not and never has been less than the fair market value of one share of Company Common Stock as of the grant date of such Company Option.

(l) Each Company Benefit Plan providing for deferred compensation that constitutes a "nonqualified deferred compensation plan" (as defined in Section 409A(d)(1) of the Code and the regulations promulgated thereunder) is, and has been, established, administered and maintained in material compliance with the requirements of Section 409A of the Code and the regulations promulgated thereunder in all material respects.

(m) No current or former employee, officer, director or independent contractor of the Company has any "gross up" agreements with the Company or other assurance of reimbursement by the Company for any Taxes imposed under Code Section 409A or Code Section 4999.

(n) No Company Benefit Plan is maintained outside of the United States.

(o) The Company has provided to Parent a true and correct list, as of the date of this Agreement, containing the names of all full-time and part-time employees, as well as their respective full-time or part-time status, and the names of all independent contractors and consultants (and indication as such), and, as applicable: (i) the annual dollar amount of all compensation (including wages, salary or fees, commissions, director's fees, fringe benefits, bonuses, profit sharing payments, and other payments or benefits of any type) payable to each person; (ii) dates of employment or service; (iii) title; (iv) any eligibility to receive severance, retention payment, change of control payment, or other similar compensation; (v) visa status, if applicable; (vi) work location; and (vii) with respect to employees, a designation of whether the employee is classified as exempt or non-exempt for purposes of the Fair Labor Standards Act, as amended ("***FLSA***") and any similar state law.

(p) The Company is not and has never been a party to, is not and has never been bound by, and does not have and has never had a duty to bargain under, any collective bargaining agreement or other Contract with a labor union, labor organization, or similar Person representing any of its employees, and there is no labor union, labor organization, or similar Person representing or, to the Knowledge of the Company, purporting to represent or seeking to represent any employees of the Company, including through the filing of a petition for representation election. There is not and has not been in the past three years, nor is there or has there been in the past three years any threat of, any strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or, to the Knowledge of the Company, any union organizing activity, against the Company. No event has occurred, and no condition or circumstance exists, that might directly or indirectly be likely to give rise to or provide a basis for the commencement of any such strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, any similar activity or dispute, or, to the Knowledge of the Company, any union organizing activity.

(q) The Company is, and since January 1, 2016 has been, in material compliance with all applicable Laws respecting labor, employment, employment practices, and terms and conditions of employment, including worker classification, discrimination, harassment and retaliation, equal employment

opportunities, fair employment practices, meal and rest periods, immigration, employee safety and health, payment of wages (including overtime wages), unemployment and workers' compensation, leaves of absence, hours of work, and termination of employment. Except as would not be reasonably likely to result in a material liability to the Company, with respect to employees of the Company, the Company, since January 1, 2016: (i) has withheld and reported all amounts required by Law or by agreement to be withheld and reported with respect to wages, salaries and other payments, benefits, or compensation to employees, (ii) is not liable for any arrears of wages (including overtime wages), severance pay or any Taxes or any penalty for failure to comply with any of the foregoing and (iii) is not liable for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Body, with respect to unemployment compensation benefits, disability, social security or other benefits or obligations for employees (other than routine payments to be made in the Ordinary Course of Business). There are no actions, suits, claims, charges, lawsuits, investigations, audits or administrative matters pending or, to the Knowledge of the Company, threatened or reasonably anticipated against the Company relating to any employee, applicant for employment, consultant, employment agreement or Company Benefit Plan (other than routine claims for benefits).

(r) Except as would not be reasonably likely to result in a material liability to the Company, with respect to each individual who currently renders services to the Company, the Company has accurately classified each such individual as an employee, independent contractor, or otherwise under all applicable Laws and, for each individual classified as an employee, the Company has accurately classified him or her as exempt or non-exempt under all applicable Laws. The Company does not have any material liability with respect to any misclassification of: (a) any Person as an independent contractor rather than as an employee, (b) any employee leased from another employer or (c) any employee currently or formerly classified as exempt under all applicable Laws.

(s) Within the preceding five (5) years, the Company has not implemented any "plant closing" or "mass layoff" of employees that would reasonably be expected to require notification under the WARN Act or any similar state or local Law, no such "plant closing" or "mass layoff" will be implemented before the Closing Date without advance notification to and approval of Parent, and there has been no "employment loss" as defined by the WARN Act or comparable state law within the ninety (90) days prior to the Closing Date.

(t) There is no Legal Proceeding, claim, unfair labor practice charge or complaint, labor dispute or grievance pending or, to the Knowledge of the Company, threatened against the Company relating to labor, employment, employment practices, or terms and conditions of employment.

2.18 **Environmental Matters**. The Company is and since January 1, 2013 has complied with all applicable Environmental Laws, which compliance includes the possession by the Company of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof, except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to be material to the Company or its business. The Company has not received since January 1, 2013 (or prior to that time, which is pending and unresolved), any written notice or other communication (in writing or otherwise), whether from a Governmental Body or other Person, that alleges that the Company is not in compliance with or has liability pursuant to any Environmental Law and, to the Knowledge of the Company, there are no circumstances that would reasonably be expected to prevent or interfere with the Company's compliance in any material respects with any Environmental Law, except where such failure to comply would not reasonably be expected to be material to the Company or its business. No current or (during the time a prior property was leased or controlled by the Company) prior property leased or controlled by the Company has had a release of or exposure to Hazardous Materials in material violation of or as would reasonably be expected to result in any material liability of the Company pursuant to Environmental Law. No consent, approval or Governmental Authorization of or registration or filing with any Governmental Body is required by Environmental Laws in connection with the execution and delivery of this Agreement or the Contemplated Transactions. Prior to the date hereof, the Company has provided or otherwise made available to Parent true and correct copies of all material environmental reports, assessments, studies and audits in the possession or control of the Company with respect to any property leased or controlled by the Company or any business operated by them.

2.19 **Insurance**. The Company has delivered or made available to Parent accurate and complete copies of all material insurance policies and all material self-insurance programs and arrangements relating to the business, assets, liabilities and operations of the Company. Each of such insurance policies is in full force and effect and the Company is in compliance in all material respects with the terms thereof. Other than customary end of policy notifications from insurance carriers, since January 1, 2016, the Company has not received any notice or other communication regarding any actual or possible: (i) cancellation or invalidation of any insurance policy; or (ii) refusal or denial of any coverage, reservation of rights or rejection of any material claim under any insurance policy. The Company has provided timely written notice to the appropriate insurance carrier(s) of each Legal Proceeding that is currently pending against the Company for which the Company has insurance coverage, and no such carrier has issued a denial of coverage or a reservation of rights with respect to any such Legal Proceeding, or informed the Company of its intent to do so.

2.20 **No Financial Advisors**. No broker, finder or investment banker is entitled to any brokerage fee, finder's fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of the Company.

2.21 **Disclosure**. The information supplied by the Company for inclusion in the Proxy Statement (including any of the Company Financials) will not, as of the date of the Proxy Statement or as of the date such information is prepared or presented, (i) contain any statement that is inaccurate or misleading with respect to any material facts, or (ii) omit to state any material fact necessary in order to make such information, in light of the circumstances under which such information will be provided, not false or misleading.

2.22 **Transactions with Affiliates.**

(a) Section 2.22(a) of the Company Disclosure Schedule (i) describes any material transactions or relationships, since January 1, 2016, between, on one hand, the Company and, on the other hand, any (A) executive officer or director of the Company or, to the Knowledge of the Company, any of such executive officer's or director's immediate family members, (B) owner of more than 5% of the voting power of the outstanding Company Capital Stock or (C) to the Knowledge of the Company, any "related person" (within the meaning of Item 404 of Regulation S-K under the Securities Act) of any such officer, director or owner (other than the Company) in the case of each of (A), (B) or (C) that is of the type that would be required to be disclosed under Item 404 of Regulation S-K under the Securities Act; and (ii) identifies each Person who is (or who may be deemed to be) an Affiliate of the Company as of the date of this Agreement.

(b) Section 2.22(b) of the Company Disclosure Schedule lists each stockholders agreement, voting agreement, registration rights agreement, co-sale agreement or other similar Contract between the Company and any holders of Company Capital Stock, including any such Contract granting any Person investor rights, rights of first refusal, rights of first offer, registration rights, director designation rights or similar rights (collectively, the "***Investor Agreements***").

2.23 **Anti-Bribery**. None of the Company or any of its directors, officers, employees or, to the Company's Knowledge, agents or any other Person acting on their behalf has directly or indirectly made any bribes, rebates, payoffs, influence payments, kickbacks, illegal payments, illegal political contributions, or other payments, in the form of cash, gifts, or otherwise, or taken any other action, in violation of the Foreign Corrupt Practices Act of 1977, the UK Bribery Act of 2010 or any other anti-bribery or anti-corruption Law (collectively, the "***Anti-Bribery Laws***"). To the Knowledge of the Company, the Company is not and has never been the subject of any investigation or inquiry by any Governmental Body with respect to potential violations of Anti-Bribery Laws.

2.24 **Disclaimer of Other Representations or Warranties.**

(a) Except as previously set forth in this Section 2 or in any certificate delivered by the Company to Parent and/or Merger Sub pursuant to this Agreement, the Company makes no representation or warranty, express or implied, at law or in equity, with respect to it or any of its assets, liabilities or operations, and any such other representations or warranties are hereby expressly disclaimed.

(b) The Company acknowledges and agrees that, except for the representations and warranties of Parent and Merger Sub set forth in Section 3, none of the Company or any of their respective

Representatives is relying on any other representation or warranty of Parent or any other Person made outside of Section 3, including regarding the accuracy or completeness of any such other representations or warranties or the omission of any material information, whether express or implied, in each case, with respect to the Contemplated Transactions.

Section 3. REPRESENTATIONS AND WARRANTIES OF PARENT AND MERGER SUB

Subject to Section 10.13(h), except (a) as set forth in the disclosure schedule delivered by Parent to the Company (the "***Parent Disclosure Schedule***") or (b) as disclosed in the Parent SEC Documents filed with the SEC at least two (2) Business Days prior to the date hereof and publicly available on the SEC's Electronic Data Gathering Analysis and Retrieval system (but (i) without giving effect to any amendment thereof filed with, or furnished to the SEC on or after the date hereof and (ii) excluding any disclosures contained under the heading "Risk Factors" and any disclosure of risks included in any "forward-looking statements" disclaimer or in any other section to the extent they are forward-looking statements or cautionary, predictive or forward-looking in nature), Parent and Merger Sub represent and warrant to the Company as follows:

3.1 **Due Organization; No Subsidiaries**.

(a) Each of Parent and Merger Sub is a corporation duly incorporated, validly existing and in good standing under the Laws of Delaware, and has all necessary corporate power and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used; and (iii) to perform its obligations under all Contracts by which it is bound. Since the date of its incorporation, Merger Sub has not engaged in any activities other than activities incident to its formation or in connection with or as contemplated by this Agreement.

(b) Parent is duly licensed and qualified to do business, and is in good standing (to the extent applicable in such jurisdiction), under the Laws of all jurisdictions where the nature of its business requires such licensing or qualification other than in jurisdictions where the failure to be so qualified individually or in the aggregate would not be reasonably expected to have a Parent Material Adverse Effect.

(c) Parent has no Subsidiaries, except for the Entities identified in Section 3.1(c) of the Parent Disclosure Schedule; and neither Parent nor any of the Entities identified in Section 3.1(c) of the Parent Disclosure Schedule owns any capital stock of, or any equity, ownership or profit sharing interest of any nature in, or controls directly or indirectly, any other Entity other than the Entities identified in Section 3.1(c) of the Parent Disclosure Schedule. Each of Parent's Subsidiaries is a corporation or other legal Entity duly organized, validly existing and, if applicable, in good standing under the Laws of the jurisdiction of its organization and has all necessary corporate or other power and authority to conduct its business in the manner in which its business is currently being conducted and to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used, except where the failure to have such power or authority would not be reasonably expected to have a Parent Material Adverse Effect.

(d) Parent is not and has not otherwise been, directly or indirectly, a party to, member of or participant in any partnership, joint venture or similar business Entity. Parent has not agreed and is not obligated to make, and is not bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other Entity. Parent has not, at any time, been a general partner of, and has not otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other Entity.

3.2 **Organizational Documents**. Parent has made available to the Company accurate and complete copies of Parent's and Merger Sub's Organizational Documents in effect as of the date of this Agreement. Neither Parent nor Merger Sub is in breach or violation of its respective Organizational Documents.

3.3 **Authority; Binding Nature of Agreement**.

(a) Each of Parent and Merger Sub has all necessary corporate power and authority to enter into and to perform its obligations under this Agreement and, subject, with respect to Parent, to receipt of the Required Parent Stockholder Vote and, with respect to Merger Sub, the adoption of this Agreement by Parent in its capacity as sole stockholder of Merger Sub, to perform its obligations hereunder and to

consummate the Contemplated Transactions. The Parent Board (at meetings duly called and held) has: (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of Parent and its stockholders; (ii) authorized, approved and declared advisable this Agreement and the Contemplated Transactions, including the issuance of shares of Parent Common Stock to the stockholders of the Company pursuant to the terms of this Agreement and the treatment of the Company Options pursuant to this Agreement; and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of Parent vote to approve the Parent Stockholder Matters. The Merger Sub Board (by unanimous written consent) has: (A) determined that the Contemplated Transactions are fair to, advisable, and in the best interests of Merger Sub and its sole stockholder; (B) authorized, approved and declared advisable this Agreement and the Contemplated Transactions; and (C) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholder of Merger Sub vote to adopt this Agreement and thereby approve the Contemplated Transactions.

(b) This Agreement has been duly executed and delivered by each of Parent and Merger Sub and, assuming the due authorization, execution and delivery by the Company, constitutes the legal, valid and binding obligation of Parent and Merger Sub, enforceable against each of Parent and Merger Sub in accordance with its terms, subject to the Enforceability Exceptions. Prior to the execution of the Parent Stockholder Support Agreements, the Parent Board approved the Parent Stockholder Support Agreements and the Contemplated Transactions.

3.4 **Vote Required**. (a) The affirmative vote of the holders of a majority of the outstanding shares of Parent Common Stock is the only vote of the holders of any class or series of Parent's capital stock necessary to approve the proposals in Section 5.3(a)(i) and (b) the affirmative vote of a majority of the votes cast at the Parent Stockholders' Meeting is the only vote of the holders of any class or series of Parent's capital stock necessary to approve the proposals in Section 5.3(a)(ii) and (iii) (the "***Required Parent Stockholder Vote***").

3.5 **Non-Contravention; Consents**. Subject to obtaining the Required Parent Stockholder Vote, the filing of the Proxy Statement with the SEC in accordance with the Exchange Act, the filing of Current Reports on Form 8-K with the SEC within four Business Days after the execution of this Agreement and the Closing Date, amending Parent's certificate of incorporation to effect the Nasdaq Reverse Split, such approvals as may be required under applicable state securities or "blue sky" laws or the rules and regulations of Nasdaq or other applicable national securities exchange or over-the-counter market, the filing of the Certificate of Merger required by the DGCL, neither (x) the execution, delivery or performance of this Agreement by Parent or Merger Sub, nor (y) the consummation of the Contemplated Transactions, will directly or indirectly (with or without notice or lapse of time):

(a) contravene, conflict with or result in a violation of any of the provisions of the Organizational Documents of Parent or Merger Sub;

(b) contravene, conflict with or result in a material violation of, or to the Knowledge of Parent give any Governmental Body or other Person the right to challenge the Contemplated Transactions or to exercise any material remedy or obtain any material relief under, any Law or any order, writ, injunction, judgment or decree to which Parent or Merger Sub, or any of the assets owned or used by Parent or Merger Sub, is subject, except as would not reasonably be expected to be material to Parent or its business;

(c) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Body the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by Parent, except as would not reasonably be expected to be material to Parent or its business;

(d) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Parent Material Contract, or give any Person the right to: (i) declare a default or exercise any remedy under any Parent Material Contract; (ii) any material payment, rebate, chargeback, penalty or change in delivery schedule under any Parent Material Contract; (iii) accelerate the maturity or performance of any Parent Material Contract; or (iv) cancel, terminate or modify any term of any Parent Material Contract, except in the case of any non-material breach, default, penalty or modification; or

(e) result in the imposition or creation of any Encumbrance upon or with respect to any asset owned or used by Parent (except for Permitted Encumbrances).

Except for (i) any Consent set forth on Section 3.5 of the Parent Disclosure Schedule under any Parent Contract, (ii) the Required Parent Stockholder Vote, (iii) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware pursuant to the DGCL and (iv) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities Laws, Parent is not and will not be required to make any filing with or give any notice to, or to obtain any Consent from, any Person in connection with (A) the execution, delivery or performance of this Agreement, the Parent Stockholder Support Agreements, and the Parent Lock-Up Agreements or (B) the consummation of the Contemplated Transactions, which if individually or in the aggregate were not given or obtained, would reasonably be expected to prevent or materially delay the ability of Parent and Merger Sub to consummate the Contemplated Transactions. The Parent Board and the Merger Sub Board have taken and will take all actions necessary to ensure that the restrictions applicable to business combinations contained in Section 203 of the DGCL are, and will be, inapplicable to the execution, delivery and performance of this Agreement, the Parent Stockholder Support Agreements, the Parent Lock-Up Agreements and to the consummation of the Contemplated Transactions. No other state Takeover Statute or similar Law applies or purports to apply to the Merger, this Agreement, the Parent Stockholder Support Agreements, the Parent Lock-Up Agreements or any of the other Contemplated Transactions.

3.6 **Capitalization**.

(a) The authorized capital stock of Parent as of the date of this Agreement consists of (i) 75,000,000 shares of Parent Common Stock, par value $0.01 per share, of which 37,312,794 shares have been issued and are outstanding as of the close of business on the Reference Date and (ii) 5,000,000 shares of preferred stock of Parent, par value $0.01 per share, of which no shares have been issued and are outstanding as of the date of this Agreement. Parent holds 112,209 shares of its capital stock in its treasury.

(b) All of the outstanding shares of Parent Common Stock have been duly authorized and validly issued, and are fully paid and nonassessable. None of the outstanding shares of Parent Common Stock is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Parent Common Stock is subject to any right of first refusal in favor of Parent. Except as contemplated herein, there is no Parent Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Parent Common Stock. Parent is not under any obligation, nor is it bound by any Contract pursuant to which it may become obligated, to repurchase, redeem or otherwise acquire any outstanding shares of Parent Common Stock or other securities. Section 3.6(b) of the Parent Disclosure Schedule accurately and completely lists all repurchase or forfeiture rights held by the Parent with respect to shares of Parent Common Stock (including shares issued pursuant to the exercise of stock options) and specifies which of those repurchase rights are currently exercisable and whether the holder of such shares of Parent Common Stock timely filed an election with the relevant Governmental Bodies under Section 83(b) of the Code with respect to such shares.

(c) Except for the Parent Stock Plans (and awards granted thereunder), Parent does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. As of the close of business on the Reference Date, 5,782,588 shares of Parent Common Stock have been reserved for issuance upon exercise of Parent Options previously granted and currently outstanding under the Parent Stock Plans and 5,485,400 shares remain available for future issuance pursuant to the Parent Stock Plans. Section 3.6(c) of the Parent Disclosure Schedule sets forth the following information with respect to each Parent Option outstanding as of the date of this Agreement: (i) the name of the optionee; (ii) the number of shares of Parent Common Stock subject to such Parent Option at the time of grant; (iii) the number of shares of Parent Common Stock subject to such Parent Option as of the date of this Agreement; (iv) the exercise price of such Parent Option; (v) the date on which such Parent Option was granted; (vi) the applicable vesting schedule, including the number of vested and unvested shares as of the date of this Agreement and any acceleration provisions; (vii) the date on which such Parent Option expires; and (viii) whether such Parent Option is intended to constitute an “incentive stock option” (as defined in the Code) or a non-qualified stock option. Parent has made available to the Company accurate and complete copies of the Parent Stock Plans and all forms of the stock option and other award agreements evidencing outstanding awards granted thereunder.

(d) Except for the Parent Stock Plans and the Parent Options set forth on Section 3.6(c) of the Parent Disclosure Schedule, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of Parent or any of its Subsidiaries; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of Parent or any of its Subsidiaries; or (iii) condition or circumstance that is reasonably likely to give rise to or provide a basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive any shares of capital stock or other securities of Parent or any of its Subsidiaries. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to Parent or any of its Subsidiaries.

(e) All outstanding shares of Parent Common Stock, Parent Options, and other securities of Parent have been issued and granted in material compliance with (i) all applicable securities Laws and other applicable Law, and (ii) all requirements set forth in applicable Contracts.

3.7 **SEC Filings; Financial Statements**.

(a) Parent has delivered or made available to the Company accurate and complete copies of all registration statements, proxy statements, Certifications (as defined below) and other statements, reports, schedules, forms and other documents filed by Parent with the SEC since January 1, 2016 (the "***Parent SEC Documents***"), other than such documents that can be obtained on the SEC's website at www.sec.gov. Since January 1, 2018, all material statements, reports, schedules, forms and other documents required to have been filed by Parent or its officers with the SEC have been so filed on a timely basis. As of the time it was filed with the SEC (or, if amended or superseded by a filing prior to the date of this Agreement, then on the date of such filing), each of the Parent SEC Documents complied in all material respects with the applicable requirements of the Securities Act or the Exchange Act (as the case may be) and, as of the time they were filed, none of the Parent SEC Documents contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The certifications and statements required by (i) Rule 13a-14 under the Exchange Act and (ii) 18 U.S.C. §1350 (Section 906 of the Sarbanes-Oxley Act) relating to the Parent SEC Documents (collectively, the "***Certifications***") are accurate and complete and comply as to form and content with all applicable Laws. As used in this Section 3.7, the term "file" and variations thereof shall be broadly construed to include any manner in which a document or information is furnished, supplied or otherwise made available to the SEC.

(b) The financial statements (including any related notes) contained or incorporated by reference in the Parent SEC Documents: (i) complied as to form in all material respects with the published rules and regulations of the SEC applicable thereto; (ii) were prepared in accordance with GAAP (except as may be indicated in the notes to such financial statements or, in the case of unaudited financial statements, except as permitted by Form 10-Q of the SEC, and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments) applied on a consistent basis unless otherwise noted therein throughout the periods indicated; and (iii) fairly present, in all material respects, the financial position of Parent as of the respective dates thereof and the results of operations and cash flows of Parent for the periods covered thereby. Other than as expressly disclosed in the Parent SEC Documents filed prior to the date hereof, there has been no material change in Parent's accounting methods or principles that would be required to be disclosed in Parent's financial statements in accordance with GAAP.

(c) Parent's independent registered accounting firm has at all times since the date Parent became subject to the applicable provisions of the Sarbanes-Oxley Act been: (i) a registered public accounting firm (as defined in Section 2(a)(12) of the Sarbanes-Oxley Act); (ii) to the Knowledge of Parent, "independent" with respect to Parent within the meaning of Regulation S-X under the Exchange Act; and (iii) to the Knowledge of Parent, in compliance with subsections (g) through (l) of Section 10A of the Exchange Act and the rules and regulations promulgated by the SEC and the Public Company Accounting Oversight Board thereunder.

(d) Since January 1, 2016 through the date of this Agreement, Parent has not received any comment letter from the SEC or the staff thereof or any correspondence from officials of Nasdaq or the staff thereof relating to the delisting or maintenance of listing of the Parent Common Stock on Nasdaq.

(e) Since January 1, 2016, there have been no formal investigations regarding financial reporting or accounting policies and practices discussed with, reviewed by or initiated at the direction of the chief executive officer, chief financial officer, principal accounting officer or general counsel of Parent, the Parent Board or any committee thereof, other than ordinary course audits or reviews of accounting policies and practices or internal controls required by the Sarbanes-Oxley Act.

(f) Parent is and since January 1, 2016 has been, in compliance in all material respects with the applicable current listing and governance rules and regulations of Nasdaq.

(g) Parent maintains, and at all times since January 1, 2018 has maintained, a system of internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and to provide reasonable assurance (i) that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, (ii) that receipts and expenditures are made only in accordance with authorizations of management and the Parent Board and (iii) regarding prevention or timely detection of the unauthorized acquisition, use or disposition of Parent's assets that could have a material effect on Parent's financial statements. Parent has evaluated the effectiveness of Parent's internal control over financial reporting as of June 30, 2019 and, to the extent required by applicable Law, presented in any applicable Parent SEC Document that is a report on Form 10-K or Form 10-Q (or any amendment thereto) its conclusions about the effectiveness of the internal control over financial reporting as of the end of the period covered by such report or amendment based on such evaluation. Parent has disclosed, based on its most recent evaluation of internal control over financial reporting, to Parent's auditors and audit committee (and made available to the Company a summary of the significant aspects of such disclosure) (A) all significant deficiencies, if any, in the design or operation of internal control over financial reporting that are reasonably likely to adversely affect Parent's ability to record, process, summarize and report financial information and (B) any known fraud that involves management or other employees who have a significant role in Parent's internal control over financial reporting. Parent has not identified, based on its most recent evaluation of internal control over financial reporting, any material weaknesses in the design or operation of Parent's internal control over financial reporting.

(h) Parent maintains "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) that are reasonably designed to ensure that all information required to be disclosed by Parent in the periodic reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods required by the SEC, and that all such information is accumulated and communicated to Parent's management as appropriate to allow timely decisions regarding required disclosure and to make the Certifications.

3.8 **Absence of Changes**. Since the date of the Parent Balance Sheet, Parent and its Subsidiaries have conducted its business only in the Ordinary Course of Business (except for the execution and performance of this Agreement and the discussions, negotiations and transactions related thereto) and there has not been any (a) Parent Material Adverse Effect or (b) action, event or occurrence that would have required consent of the Company pursuant to Section 4.1(b) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

3.9 **Absence of Undisclosed Liabilities**. As of the date hereof, Parent does not have any Liability, individually or in the aggregate, of a type required to be recorded or reflected on a balance sheet or disclosed in the footnotes thereto under GAAP, except for: (a) Liabilities disclosed, reflected or reserved against in the Parent Balance Sheet; (b) Liabilities that have been incurred by Parent since the date of the Parent Balance Sheet in the Ordinary Course of Business; (c) Liabilities for performance of obligations of Parent under Parent Contracts; (d) Liabilities incurred in connection with the Contemplated Transactions; (e) Liabilities which would not, individually or in the aggregate, reasonably be expected to be material to the Parent; and (f) Liabilities described in Section 3.9 of the Parent Disclosure Schedule.

3.10 **Title to Assets**. Parent owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all tangible properties or tangible assets and equipment used or held for use in its business or operations or purported to be owned by it that are material to Parent or its business, including: (a) all tangible assets reflected on the Parent Balance Sheet; and (b) all other tangible assets reflected in the books and records of Parent as being owned by Parent. All of such assets are owned or, in the case of leased assets, leased by Parent free and clear of any Encumbrances, other than Permitted Encumbrances.

3.11 **Real Property; Leasehold**. Parent does not own and has never owned any real property. Parent has made available to the Company (a) an accurate and complete list of all real properties with respect to which Parent directly or indirectly holds a valid leasehold interest as well as any other real estate that is in the possession of or leased by Parent and (b) copies of all leases under which any such real property is possessed (the "***Parent Real Estate Leases***"), each of which is in full force and effect, with no existing material default thereunder. Parent's use and operation of each such leased property conforms to all applicable Laws in all material respects, and Parent has exclusive possession of each such leased property and has not granted any occupancy rights to tenants or licensees with respect to such leased property. In addition, each such leased property is free and clear of all Encumbrances other than Permitted Encumbrances.

3.12 **Intellectual Property.**

(a) Section 3.12(a) of the Parent Disclosure Schedule identifies each item of material Parent IP that is the subject of a registration or application in any jurisdiction ("***Parent Registered IP***"), including, with respect to each patent and patent application: (i) the name of the applicant/registrant; (ii) the jurisdiction of application/registration; (iii) the application or registration number; and (iv) any other co-owners. To the Knowledge of Parent, each of the patents and patent applications included in the Section 3.12(a) of the Parent Disclosure Schedule properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States. To the Knowledge of Parent, as of the date of this Agreement, no cancellation, interference, opposition, reissue, reexamination or other proceeding of any nature (other than office actions or similar communications issued by any Governmental Body in the ordinary course of prosecution of any pending applications for registration) is pending or threatened in writing, in which the scope, validity, enforceability or ownership of any Parent IP is being or has been contested or challenged. To the Knowledge of Parent, each item of Parent IP is valid and enforceable, and with respect to Parent Registered IP, subsisting. Except as set forth in Section 2.12(a) of the Parent Disclosure Schedule, there are no actions that must be taken within ninety (90) days of the Closing, the failure of which will result in the abandonment, lapse or cancellation of any Parent Registered IP.

(b) Except as has not had and would not reasonably be expected to have, individually or in the aggregate, a Parent Material Adverse Effect, Parent exclusively owns, is the sole assignee of, or has exclusively licensed all material Parent IP (other than as disclosed on Section 3.12(b) of the Parent Disclosure Schedule), free and clear of all Encumbrances other than Permitted Encumbrances. The Parent IP and the Intellectual Property Rights licensed to the Parent pursuant to a valid, enforceable written agreement constitute all Intellectual Property Rights used in, material to or otherwise necessary for the operation of the Parent's business as currently conducted. To the Knowledge of Parent, each Parent Associate involved in the creation or development of any material Parent IP, pursuant to such Parent Associate's activities on behalf of Parent, has signed a valid and enforceable written agreement containing an assignment of such Parent Associate's rights in such Parent IP to Parent. Each Parent Associate who has or has had access to the Parent's trade secrets or confidential information has signed a valid and enforceable written agreement containing confidentiality provisions protecting the Parent IP, trade secrets and confidential information. Parent has taken commercially reasonable steps to protect and preserve the confidentiality of its trade secrets and confidential information.

(c) To the Knowledge of Parent, no funding, facilities or personnel of any Governmental Body or any university, college, research institute or other educational institution has been used to create Parent IP, except for any such funding or use of facilities or personnel that does not result in such Governmental Body or institution obtaining ownership rights or a license to such Parent IP or the right to receive royalties for the practice of such Parent IP.

(d) Section 3.12(d) of Parent Disclosure Schedule sets forth each license agreement pursuant to which the Parent (i) is granted a license under any material Intellectual Property Right owned by any third party that is used by Parent in its business as currently conducted (each a "***Parent In-bound License***") or (ii) grants to any third party a license under any material Parent IP or material Intellectual Property Right licensed to the Parent under a Parent In-bound License (each a "***Parent Out-bound License***") (provided, that, Parent In-bound Licenses shall not include, when entered into in the Ordinary Course of Business, material transfer agreements, services agreements, clinical trial agreements, agreements with Parent Associates, commercially available Software-as-a-Service offerings or off-the-shelf software licenses; and Parent Out-bound Licenses shall not include, when entered into in the Ordinary Course of Business, material transfer agreements, clinical trial agreements, services agreements, or non-exclusive outbound licenses). All Parent In-bound Licenses and Parent Out-bound Licenses are in full force and effect and are valid, enforceable and binding obligations of the Parent and, to the Knowledge of Parent, each other party to such Parent In-bound Licenses or Parent Out-bound Licenses. Neither Parent, nor to the Knowledge of the Parent, any other party to such Parent In-bound Licenses or Parent Out-bound Licenses, is in material breach under any Parent In-bound Licenses or Parent Out-bound Licenses.

(e) To the Knowledge of Parent: (i) the operation of the businesses of Parent as currently conducted does not infringe, misappropriate or otherwise violate any Intellectual Property Rights of any other Person and (ii) no other Person is infringing, misappropriating or otherwise violating any Parent IP. No Legal Proceeding is pending (or, to the Knowledge of Parent, is threatened in writing) (A) against Parent alleging that the operation of the businesses of Parent infringes or constitutes the misappropriation or other violation of any Intellectual Property Rights of another Person or (B) by Parent alleging that another Person has infringed, misappropriated or otherwise violated any of Parent IP or any Intellectual Property Rights exclusively licensed to Parent. Since January 1, 2016, Parent has not received any written notice or other written communication alleging that the operation of the business of Parent infringes or constitutes the misappropriation or other violation of any Intellectual Property Right of another Person.

(f) None of Parent IP or, to the Knowledge of Parent, any material Intellectual Property Rights exclusively licensed to Parent is subject to any pending or outstanding injunction, directive, order, judgment or other disposition of dispute that adversely and materially restricts the use, transfer, registration or licensing by Parent of any such Parent IP or material Intellectual Property Rights exclusively licensed to Parent or its Subsidiaries.

(g) To the Knowledge of Parent, Parent and the operation of Parent's business are in substantial compliance with all Laws pertaining to data privacy and data security of Sensitive Data (as defined in Section 2.12(g)), except to the extent that such noncompliance has not and would not reasonably be expected to have a Parent Material Adverse Effect. To the Knowledge of Parent, since January 1, 2016, there have been (i) no material losses or thefts of data or security breaches relating to Sensitive Data used in the business of Parent, (ii) no violations of any security policy of Parent regarding any such Sensitive Data used in the business of Parent, (iii) no unauthorized access, unauthorized use or unintended or improper disclosure of any Sensitive Data used in the business of Parent, in each case of (i) through (iii), except as would not reasonably be expected to, individually or in the aggregate, have a Parent Material Adverse Effect. Parent has taken reasonable steps and implemented reasonable disaster recovery and security plans and procedures to protect the information technology systems used in, material to or necessary for operation of the Parent's business as currently conducted from unauthorized use or access. To the Knowledge of the Parent, there have been no material malfunctions or unauthorized intrusions or breaches of the information technology systems used in, material to or necessary for the operation of the Parent's business as currently conducted.

3.13 **Agreements, Contracts and Commitments**.

(a) Section 3.13(a) of the Parent Disclosure Schedule lists the following Parent Contracts in effect as of the date of this Agreement (and, except with respect to clauses (xii) and (xiii) below, other than any Benefit Plans) (each, a "***Parent Material Contract***" and collectively, the "***Parent Material Contracts***"):

(i) each Parent Contract relating to any agreement of indemnification or guaranty not entered into in the Ordinary Course of Business;

(ii) each Parent Contract containing: (A) any covenant limiting the freedom of Parent to engage in any line of business or compete with any Person; (B) any most-favored pricing arrangement; (C) any exclusivity provision; or (D) any non-solicitation provision, in each case, except for restrictions that would not materially affect the ability of Parent to conduct its business;

(iii) each Parent Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of $75,000 pursuant to its express terms and not cancelable without penalty;

(iv) each Parent Contract relating to the disposition or acquisition of material assets or any ownership interest in any Entity, in each case, involving payments in excess of $75,000, other than Parent Contracts in which the applicable acquisition or disposition has been consummated and there are no material ongoing obligations;

(v) each Parent Contract relating to any mortgages, indentures, loans, notes or credit agreements, security agreements or other agreements or instruments relating to the borrowing of money or extension of credit or creating any material Encumbrances with respect to any assets of Parent or any loans or debt obligations with officers or directors of Parent;

(vi) each Parent Contract requiring payment by or to Parent after the date of this Agreement in excess of $75,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of Parent; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, development or other agreement currently in force under which Parent has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which Parent has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by Parent; or (D) any Parent Contract with any third party providing any services relating to the manufacture or production of any product, service or technology of Parent or any Parent Contract to sell, distribute or commercialize any products or service of Parent;

(vii) each Parent Contract with any financial advisor, broker, finder, investment banker or other similar Person, providing advisory services to Parent in connection with the Contemplated Transactions;

(viii) each Parent Real Estate Lease;

(ix) each Contract with any Governmental Body (other than clinical trial agreements for clinical trial studies, cooperative research and development agreements and confidentiality agreements);

(x) each Parent Out-bound License and Parent In-bound License, and each Parent Contract containing a covenant not to sue or otherwise enforce any Intellectual Property Rights;

(xi) each Parent Contract containing any royalty, dividend or similar arrangement based on the revenues or profits of Parent;

(xii) each (A) Parent Contract, offer letter, employment agreement or other agreement with any employee that (1) is not immediately terminable at will by Parent without advance notice, severance, or other cost or liability, or (2) provides for retention payments, change of control payments, severance, accelerated vesting, or any payment or benefit that may or will become due as a result of the Merger (whether alone or in connection with any other event) and (B) each Parent Contract, independent contractor agreement, or other agreement with any consultant or service provider that (1) is not immediately terminable at will by the Company without more than 30 days' prior notice, severance, or other cost or liability or (2) provides for retention payments, change of control payments, severance, accelerated vesting or any payment or benefit that may or will become due as a result of the Merger (whether alone or in connection with any other event);

(xiii) each Parent Contract providing any option to receive a license or other right, any right of first negotiation, any right of first refusal or any similar right to any Person related to any material Parent IP or material Intellectual Property Right licensed to the Parent under a Parent In-bound License;

(xiv) each Parent Contract entered into in settlement of any legal proceeding or other dispute; or

(xv) any other Parent Contract that is not terminable at will (with no penalty or payment) by Parent and (A) which involves payment or receipt by Parent after the date of this Agreement under any such agreement, Contract or commitment of more than $75,000 in the aggregate, or obligations after the date of this Agreement in excess of $75,000 in the aggregate, or (B) that is material to the business or operations of Parent.

(b) Parent has delivered or made available to the Company complete copies of all Parent Material Contracts, including all amendments thereto. There are no Parent Material Contracts that are not in written form. Parent has not, nor, to Parent's Knowledge, as of the date of this Agreement, has any other party to a Parent Material Contract, breached, violated or defaulted under, or received notice that it breached, violated or defaulted under, any of the terms or conditions of any Parent Material Contract in such manner as would permit any other party to cancel or terminate any such Parent Material Contract, or would permit any other party to seek damages which would reasonably be expected to be material to Parent or its business. As to Parent, as of the date of this Agreement, each Parent Material Contract is valid, binding, enforceable and in full force and effect, subject to the Enforceability Exceptions. No Person is renegotiating, or has a right pursuant to the terms of any Parent Material Contract to change, any material amount paid or payable to Parent under any Parent Material Contract or any other material term or provision of any Parent Material Contract.

3.14 **Compliance; Permits**.

(a) Parent is, and since January 1, 2016 has been, in compliance in all material respects with all applicable Laws, including the FDCA, the FDA regulations adopted thereunder, the PHSA and its implementing regulations and any other similar Law administered or promulgated by the FDA or other Drug Regulatory Agency, except for any noncompliance, either individually or in the aggregate, which would not be material to Parent. To the Knowledge of Parent, no investigation, claim, suit, proceeding, audit or other action by any Governmental Body is pending or threatened against Parent. There is no agreement, judgment, injunction, order or decree binding upon Parent which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of Parent, any acquisition of material property by Parent or the conduct of business by Parent as currently conducted, (ii) is reasonably likely to have an adverse effect on Parent's ability to comply with or perform any covenant or obligation under this Agreement or (iii) is reasonably likely to have the effect of preventing, delaying, making illegal or otherwise interfering with the Contemplated Transactions.

(b) Parent holds all required Governmental Authorizations which are material to the operation of the business of Parent as currently conducted (the "***Parent Permits***"). Section 3.14(b) of the Parent Disclosure Schedule identifies each Parent Permit. Parent is in material compliance with the terms of the Parent Permits. No Legal Proceeding is pending or, to the Knowledge of Parent, threatened, which seeks to revoke, limit, suspend, or materially modify any Parent Permit.

(c) To the Knowledge of Parent, there are no proceedings pending or threatened against Parent with respect to an alleged material violation by Parent of the FDCA, FDA regulations adopted thereunder, the Public Health Service Act or any other similar Law administered or promulgated by any Drug Regulatory Agency.

(d) Parent holds all required Governmental Authorizations issuable by any Drug Regulatory Agency necessary or material to the conduct of the business of the Parent as currently conducted (collectively, the "***Parent Regulatory Permits***") and no such Parent Regulatory Permit has been (i) revoked, withdrawn, suspended, canceled or terminated or (ii) modified in any adverse manner. Parent is in compliance in all material respects with the Parent Regulatory Permits and has not received any written notice or other written communication, or to the Knowledge of Parent, any other communication from any Drug Regulatory Agency regarding (A) any material violation of or failure to comply materially with any term or requirement of any Parent Regulatory Permit or (B) any revocation, withdrawal, suspension, cancellation, termination or material modification of any Parent Regulatory Permit. Parent has complied in

all material respects with the ICH E9 Guidance for Industry: Statistical Principles for Clinical Trials in the management of the clinical data that have been presented to the Company. To the Knowledge of Parent, there are no facts that would be reasonably likely to result in any warning, untitled or notice of violation letter or Form FDA-483 from the FDA.

(e) All clinical, pre-clinical and other studies and tests conducted by or on behalf of, or sponsored by, Parent, or in which Parent or its respective current products or product candidates have participated, were and, if still pending, are being conducted in all material respects in accordance with standard medical and scientific research procedures and in compliance in all material respects with the applicable regulations of any applicable Drug Regulatory Agency and other applicable Law, as applicable, including the GCP Regulations under 21 C.F.R. Parts 50, 54, 56, 58 and 312. No preclinical or clinical trial conducted by or on behalf of Parent has been terminated or suspended prior to completion for safety or non-compliance reasons. Since January 1, 2016, Parent has not received any notices, correspondence, or other communications from any Drug Regulatory Agency requiring, or to the Knowledge of Parent threatening to initiate, the termination or suspension of any clinical studies conducted by or on behalf of, or sponsored by, Parent or in which Parent or its current products or product candidates have participated.

(f) To the Knowledge of Parent, Parent is not the subject of any pending or threatened investigation in respect of its business or products by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto. To the Knowledge of Parent, neither Parent nor any of its officers, employees or agents have committed any acts, made any statement, or has not failed to make any statement, in each case in respect of its business or products that would violate the FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy, and any amendments thereto. Parent or any of its officers, employees or, to the Knowledge of Parent, agents has not been convicted of any crime or engaged in any conduct that could result in a debarment or exclusion (i) under 21 U.S.C. Section 335a or (ii) any similar applicable Law. No debarment or exclusionary claims, actions, proceedings or investigations in respect of their business or products are pending or, to the Knowledge of Parent, threatened against Parent or any of its officers, employees or, to the Knowledge of Parent, agents.

(g) Neither Parent, nor any of its officers, directors, employees or agents has been, is, or is in anticipation of being (based on a conviction by the courts or a finding of fault by a regulatory authority): (a) debarred pursuant to the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335a), as amended from time to time; (b) disqualified from participating in clinical trials pursuant to 21 C.F.R. §312.70, as amended from time to time; (c) disqualified as a testing facility under 21 C.F.R. Part 58, Subpart K, as amended from time to time; (d) excluded, debarred or suspended from or otherwise ineligible to participate in a "Federal Health Care Program" as defined in 42 U.S.C. 1320a-7b(f), as amended from time to time, or any other governmental payment, procurement or non-procurement program; or (e) included on the HHS/OIG List of Excluded Individuals/Entities, the General Services Administration's List of Parties Excluded from Federal Programs, or the FDA Debarment List. Parent is not using, nor has it ever used, in any capacity any Person that has ever been, is currently, or to the Knowledge of Parent is the subject of a proceeding that could lead to the Parent or its officers, directors, employees or agents becoming, as applicable, a Debarred Entity, a Debarred Individual, an Excluded Entity, an Excluded Individual, or a Convicted Entity or a Convicted Individual, nor are they listed on the FDA's Disqualified/Restricted List. The Parent, nor any of its officers, directors, employees or agents, has been excluded or threatened with exclusion under state or federal statutes or regulations, including under 42 U.S.C. § 1320a-7 or relevant regulations in 42 C.F.R. Part 1001, or assessed or threatened with assessment of civil money penalties pursuant to 42 C.F.R. Part 1003. Neither the Parent nor to its knowledge its officers, directors, employees or agents has taken any action that would now or in the future constitute an improper inducement under federal or state healthcare laws.

(h) Parent is not a Covered Entity governed by HIPAA, but each of its health plans, if required, has complied in all material respects with all Laws relating to HIPAA, including the standards for the privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164, Subparts A and E, the standards for the protection of Electronic Protected Health Information set forth at 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subpart A and Subpart C, the standards for transactions and code sets used in electronic transactions at 45 C.F.R. Part 160, Subpart A and Part 162, and the standards for Breach Notification for

Unsecured Protected Health Information at 45 C.F.R. Part 164, Subpart D, all as amended from time to time. Each of Parent's health plans has entered into, where required, and are in compliance in all material respects with the terms of all Business Associate Agreements to which Parent has signed as plan sponsor where the plan is a party or otherwise bound. Each of Parent's health plans, where required, has created and maintained written policies and procedures to protect the privacy of all protected health information, provide training to all employees and agents as required under HIPAA, and have implemented security procedures, including physical, technical and administrative safeguards, to protect all personal information and Protected Health Information stored or transmitted in electronic form. Parent has not received written notice from the Office for Civil Rights for the U.S. Department of Health and Human Services or any other Governmental Body of any allegation regarding its failure to comply with HIPAA or any other state law or regulation applicable to the protection of individually identifiable health information or personally identifiable information. No successful Security Incident, Breach of Unsecured Protected Health Information or breach of personally identifiable information under applicable state or federal laws have occurred with respect to information maintained or transmitted to Parent, or an agent or third party subject to a Business Associate Agreement with Parent. If required, Parent is currently submitting, receiving and handling or is capable of submitting receiving and handling transactions in accordance with the Standard Transaction Rule. All capitalized terms in this Section 3.14(f) not otherwise defined in this Agreement shall have the meanings set forth under HIPAA.

3.15 **Legal Proceedings; Orders**.

(a) As of the date of this Agreement, to the Knowledge of the Parent, there is no material pending Legal Proceeding and no Person has threatened in writing to commence any Legal Proceeding: (i) that involves (A) Parent, (B) any Parent Associate (in his or her capacity as such) or (C) any of the material assets owned or used by Parent; or (ii) that challenges, or that would have the effect of preventing, delaying, making illegal or otherwise interfering with, the Contemplated Transactions.

(b) Since January 1, 2016 through the date of this Agreement, no Legal Proceeding has been pending against Parent that resulted in material liability to Parent.

(c) There is no order, writ, injunction, judgment or decree to which Parent, or any of the material assets owned or used by Parent, is subject. To the Knowledge of Parent, no officer of Parent is subject to any order, writ, injunction, judgment or decree that prohibits such officer or employee from engaging in or continuing any conduct, activity or practice relating to the business of Parent or to any material assets owned or used by Parent.

3.16 **Tax Matters**.

(a) Parent and Merger Sub have timely filed all income Tax Returns and other material Tax Returns that they were required to file under applicable Law. All such Tax Returns are correct and complete in all material respects and have been prepared in compliance with all applicable Law. No written claim has ever been made by any Governmental Body in any jurisdiction where Parent or Merger Sub does not file a particular Tax Return or pay a particular Tax that Parent or Merger Sub is subject to taxation by that jurisdiction.

(b) All income and other material Taxes due and owing by Parent or Merger Sub on or before the date hereof (whether or not shown on any Tax Return) have been fully paid. The unpaid Taxes of Parent and Merger Sub did not, as of the date of the Parent Balance Sheet, materially exceed the reserve for Tax liability (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax items) set forth on the face of the Parent Balance Sheet. Since the Parent Balance Sheet Date, neither Parent nor Merger Sub has incurred any material Liability for Taxes outside the Ordinary Course of Business.

(c) All Taxes that Parent or Merger Sub are or were required by Law to withhold or collect have been duly and timely withheld or collected in all material respects on behalf of its respective employees, independent contractors, stockholders, lenders, customers or other third parties and, have been timely paid to the proper Governmental Body or properly set aside in accounts for this purpose.

(d) There are no Encumbrances for material Taxes (other than Permitted Encumbrances) upon any of the assets of Parent or Merger Sub.

(e) No deficiencies for income or other material Taxes with respect to Parent or Merger Sub have been claimed, proposed or assessed by any Governmental Body in writing. There are no pending or ongoing, and to the Knowledge of Parent, threatened audits, assessments or other actions for or relating to any liability in respect of a material amount of Taxes of Parent or Merger Sub. Neither Parent nor Merger Sub (or any of their predecessors) has waived any statute of limitations in respect of any income or other material Taxes or agreed to any extension of time with respect to any income or other material Tax assessment or deficiency.

(f) Parent has not been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(g) Neither Parent nor Merger Sub is a party to any Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, or similar agreement or arrangement, other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes.

(h) Neither Parent nor Merger Sub will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any Tax period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for Tax purposes filed on or prior to the Closing Date; (ii) use of an improper method of accounting for a Tax period ending on or prior to the Closing Date; (iii) "closing agreement" as described in Section 7121 of the Code (or any similar provision of state, local or foreign Law) executed on or prior to the Closing Date; (iv) intercompany transaction or excess loss account described in Treasury Regulations under Section 1502 of the Code (or any similar provision of state, local or foreign Law) entered into on or prior to the Closing Date; (v) installment sale or open transaction disposition made on or prior to the Closing Date; (vi) prepaid amount received on or prior to the Closing Date; or (vii) election under Section 108(i) of the Code (or any similar provision of state, local or foreign Law) made on or prior to the Closing Date. Parent has not made any election under Section 965(h) of the Code.

(i) Neither Parent nor Merger Sub has ever been (i) a member of a consolidated, combined or unitary Tax group (other than such a group the common parent of which is Parent) or (ii) a party to any joint venture, partnership, or other arrangement that is treated as a partnership for U.S. federal income Tax purposes. Neither Parent nor Merger Sub has any Liability for any material Taxes of any Person (other than Parent and Merger Sub) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Law), or as a transferee or successor.

(j) Neither Parent nor Merger Sub has, since January 1, 2016, distributed stock of another Person, or had its stock distributed by another Person, in a transaction that was purported or intended to be governed in whole or in part by Section 355 of the Code or Section 361 of the Code (or any similar provisions of state, local or foreign Law).

(k) Parent and Merger Sub (i) are, and since their formation have been, domestic corporations for United States federal income tax purpose; and (ii) has never had a permanent establishment (within the meaning of an applicable Tax treaty) or otherwise had an office or fixed place of business in a country other than the United States.

(l) Neither Parent nor Merger Sub has participated in or been a party to a transaction that, as of the date of this Agreement, constitutes a "listed transaction" that is required to be reported to the IRS pursuant to Section 6011 of the Code and applicable Treasury Regulations thereunder.

(m) Neither Parent nor Merger Sub has taken or agreed to take any action or knows of any fact that would reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment.

For purposes of this Section 3.16, each reference to Parent or Merger Sub shall be deemed to include any Person that was liquidated into, merged with, or is otherwise a predecessor to, Parent or Merger Sub, respectively.

3.17 **Employee and Labor Matters; Benefit Plans**.

(a) Section 3.17(a) of the Parent Disclosure Schedule is a list of all Parent Benefit Plans, including, without limitation, each Parent Benefit Plan that provides for retirement, change in control, stay or retention

deferred compensation, incentive compensation, severance or retiree medical or life insurance benefits. "***Parent Benefit Plan***" means each (i) "employee benefit plan" as defined in Section 3(3) of ERISA and (ii) other pension, retirement, deferred compensation, excess benefit, profit sharing, bonus, incentive, equity or equity-based (other than individual Parent Options made pursuant to the Parent's standard forms, in which case only representative standard forms of such stock option agreements shall be scheduled), phantom equity, employment (other than individual employment agreements made pursuant to Parent's standard forms, in which case only representative standard forms of such employment agreements shall be scheduled), offer letter (other than individual offer letters made pursuant to Parent's standard forms, in which case only representative standard forms of such offers shall be scheduled), consulting, severance, change-of-control, retention, health, life, disability, group insurance, paid-time off, holiday, welfare and fringe benefit plan, program, contract, or arrangement (whether written or unwritten, qualified or nonqualified, funded or unfunded and including any that have been frozen), in any case, maintained, contributed to, or required to be contributed to, by Parent or any of its subsidiaries for the benefit of any current or former employee, director, officer or independent contractor of Parent or under which Parent has any actual or contingent liability (including, without limitation, as to the result of it being treated as a single employer under Code Section 414 with any other person).

(b) As applicable with respect to each Parent Benefit Plan, Parent has made available to the Company, true and complete copies of (i) each Parent Benefit Plan, including all amendments thereto, and in the case of an unwritten Parent Benefit Plan, a written description thereof, (ii) all current trust documents, investment management contracts, custodial agreements, administrative services agreements and insurance and annuity contracts relating thereto, (iii) the current summary plan description and each summary of material modifications thereto, (iv) the most recently filed annual reports with any Governmental Body (*e.g.*, Form 5500 and all schedules thereto), (v) the most recent IRS determination, opinion or advisory letter, (vi) the most recent summary annual reports, nondiscrimination testing reports, actuarial reports, financial statements and trustee reports, and (vii) all material records, notices and filings concerning IRS or Department of Labor or other Governmental Body audits or investigations.

(c) Each Parent Benefit Plan has been maintained, operated and administered in compliance in all material respects with its terms and any related documents or agreements and the applicable provisions of ERISA, the Code and all other Laws.

(d) The Parent Benefit Plans that are "employee pension benefit plans" within the meaning of Section 3(2) of ERISA and which are intended to meet the qualification requirements of Section 401(a) of the Code have received determination or opinion letters from the IRS on which they may currently rely to the effect that such plans are qualified under Section 401(a) of the Code and the related trusts are exempt from federal income Taxes under Section 501(a) of the Code, respectively, and to the Knowledge of Parent nothing has occurred that would reasonably be expected to materially adversely affect the qualification of such Parent Benefit Plan or the tax exempt status of the related trust.

(e) Neither Parent nor any Parent ERISA Affiliate maintains, contributes to, is required to contribute to, or has any actual or contingent liability with respect to, (i) any "employee pension benefit plan" (within the meaning of Section 3(2) of ERISA) that is subject to Title IV or Section 302 of ERISA or Section 412 of the Code, (ii) any "multiemployer plan" (within the meaning of Section 3(37) of ERISA), or (iii) any "multiple employer plan" (within the meaning of Section 413 of the Code). No Parent Benefit Plan is a self-funded group health plan that is a "multiple employer welfare arrangement" (within the meaning of Section 3(40) of ERISA).

(f) There are no pending audits or investigations by any Governmental Body involving any Parent Benefit Plan, and no pending or, to the Knowledge of Parent, threatened claims (except for individual claims for benefits payable in the normal operation of the Parent Benefit Plans), suits or proceedings involving any Parent Benefit Plan, any fiduciary thereof or service provider thereto, in any case, except as would not be reasonably expected to result in material liability to Parent. All contributions and premium payments required to have been made under any of the Parent Benefit Plans or by applicable Law (without regard to any waivers granted under Section 412 of the Code), have been timely made in all material respects and neither Parent nor any Parent ERISA Affiliate has any material liability for any unpaid contributions with respect to any Parent Benefit Plan.

(g) Neither Parent or any Parent ERISA Affiliates, nor to the Knowledge of Parent, any fiduciary, trustee or administrator of any Parent Benefit Plan, has engaged in, or in connection with the Contemplated Transactions will engage in, any transaction with respect to any Parent Benefit Plan which would subject any such Parent Benefit Plan, Parent or Parent ERISA Affiliates to a material Tax, material penalty or material liability for a "prohibited transaction" under Section 406 of ERISA or Section 4975 of the Code.

(h) No Parent Benefit Plan provides death, medical, dental, vision, life insurance or other welfare benefits beyond termination of service or retirement other than coverage mandated by Law and neither Parent nor any Parent ERISA Affiliates has made a written or oral representation promising the same.

(i) Neither the execution of this Agreement nor the performance of the Contemplated Transactions will either alone or in connection with any other event(s) (i) result in any payment becoming due to any current or former employee, director, officer, or independent contractor of Parent, (ii) increase any amount of compensation or benefits otherwise payable under any Parent Benefit Plan, (iii) result in the acceleration of the time of payment, funding or vesting of any benefits under any Parent Benefit Plan, (iv) require any contribution or payment to fund any obligation under any Parent Benefit Plan or (v) limit the right to merge, amend or terminate any Parent Benefit Plan that is subject to ERISA.

(j) Neither the execution of this Agreement nor the performance of the Contemplated Transactions (either alone or when combined with the occurrence of any other event, including without limitation, a termination of employment) will result in the receipt or retention by any Person who is a "disqualified individual" (within the meaning of Code Section 280G) with respect to Parent of any payment or benefit under any Parent Benefit Plan that is or could be characterized as a "parachute payment" (within the meaning of Code Section 280G), determined without regard to the application of Code Section 280G(b)(5).

(k) The exercise price of each Parent Option granted to a U.S. taxpayer is not, never has been, less than the fair market value of one share of Parent Common Stock as of the grant date of such Parent Option.

(l) Each Parent Benefit Plan providing for deferred compensation that constitutes a "nonqualified deferred compensation plan" (as defined in Section 409A(d)(1) of the Code and the regulations promulgated thereunder) is, and has been, established, administered and maintained in material compliance with the requirements of Section 409A of the Code and the regulations promulgated thereunder in all material respects.

(m) No current or former employee, officer, director or independent contractor of Parent has any "gross up" agreements with the Parent or other assurance of reimbursement by the Parent for any Taxes imposed under Code Section 409A or Code Section 4999.

(n) No Parent Benefit Plan is maintained outside of the United States.

(o) Parent has provided to the Company a true and correct list, as of the date of this Agreement, containing the names of all full-time and part-time employees, as well as their respective full-time or part-time status, and the names of all independent contractors and consultants (and indication as such), and, as applicable: (i) the annual dollar amount of all compensation (including wages, salary or fees, commissions, director's fees, fringe benefits, bonuses, profit sharing payments, and other payments or benefits of any type) payable to each person; (ii), dates of employment or service; (iii) title; (iv) any eligibility to receive severance, notice of termination, retention payment, change of control payment, or other similar compensation; (v) visa status, if applicable; (vi) work location; and (vii) with respect to employees, a designation of whether the employee is classified as exempt or non-exempt for purposes of the FLSA and any similar state law.

(p) Parent is not and never has been a party to, bound by, or has a duty to bargain under, any collective bargaining agreement or other Contract with a labor union, labor organization, or similar Person representing any of its employees, and there is no labor union, labor organization, or similar Person representing or, to the Knowledge of Parent, purporting to represent or seeking to represent any employees of Parent, including through the filing of a petition for representation election. There is not and has not been in the past three years, nor is there or has there been in the past three years any threat of, any strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or, to the Knowledge of Parent, any union organizing activity, against Parent or any of its Subsidiaries. No event has occurred, and no condition or circumstance exists, that might directly or

indirectly be likely to give rise to or provide a basis for the commencement of any such strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, any similar activity or dispute, or, to the Knowledge of Parent, any union organizing activity.

(q) Parent is, and since January 1, 2016 has been, in material compliance with all applicable Laws respecting labor, employment, employment practices, and terms and conditions of employment, including worker classification, discrimination, harassment and retaliation, equal employment opportunities, fair employment practices, meal and rest periods, immigration, employee safety and health, payment of wages (including overtime wages), unemployment and workers' compensation, leaves of absence, hours of work, and termination of employment. Except as would not be reasonably likely to result in a material liability to Parent, with respect to employees of Parent, Parent, since January 1, 2016: (i) has withheld and reported all amounts required by Law or by agreement to be withheld and reported with respect to wages, salaries and other payments, benefits, or compensation to employees; (ii) is not liable for any arrears of wages (including overtime wages), severance pay or any Taxes or any penalty for failure to comply with any of the foregoing; and (iii) is not liable for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Body, with respect to unemployment compensation benefits, disability, social security or other benefits or obligations for employees (other than routine payments to be made in the Ordinary Course of Business). There are no actions, suits, claims, charges, lawsuits, investigations, audits or administrative matters pending or, to the Knowledge of the Company, threatened or reasonably anticipated against Parent relating to any employee, applicant for employment, consultant, employment agreement or Parent Benefit Plan (other than routine claims for benefits).

(r) Except as would not be reasonably likely to result in a material liability to Parent, with respect to each individual who currently renders services to Parent, Parent has accurately classified each such individual as an employee, independent contractor, or otherwise under all applicable Laws and, for each individual classified as an employee, Parent has accurately classified him or her as exempt or non-exempt under all applicable Laws. Parent has no material liability with respect to any misclassification of: (i) any Person as an independent contractor rather than as an employee, (ii) any employee leased from another employer, or (iii) any employee currently or formerly classified as exempt under all applicable Laws.

(s) Within the preceding five (5) years, the Company has not implemented any "plant closing" or "mass layoff" of employees that would reasonably be expected to require notification under the WARN Act or any similar state or local law. No "plant closing" or "mass layoff" will be implemented before the Closing Date without advance notification to and approval of Company, and there has been no "employment loss" as defined by the WARN Act or comparable state law within the ninety (90) days prior to the Closing Date.

(t) There is no Legal Proceeding, claim, unfair labor practice charge or complaint, labor dispute or grievance pending or, to the Knowledge of Parent, threatened against Parent relating to labor, employment, employment practices, or terms and conditions of employment.

3.18 **Environmental Matters**. Parent is and since January 1, 2013 has complied with all applicable Environmental Laws, which compliance includes the possession by Parent of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof, except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to be material to Parent or its business. Parent has not received since January 1, 2013 (or prior to that time, which is pending and unresolved), any written notice or other communication (in writing or otherwise), whether from a Governmental Body or other Person, that alleges that Parent is not in compliance with or has liability pursuant to any Environmental Law and, to the Knowledge of Parent, there are no circumstances that would reasonably be expected to prevent or interfere with Parent's compliance in any material respects with any Environmental Law, except where such failure to comply would not reasonably be expected to be material to Parent or its business. No current or (during the time a prior property was leased or controlled by Parent) prior property leased or controlled by Parent has had a release of or exposure to Hazardous Materials in material violation of or as would reasonably be expected to result in any material liability of Parent pursuant to Environmental Law. No consent, approval or Governmental Authorization of or registration or filing with any Governmental Body is required by Environmental Laws in connection with the execution and delivery of this Agreement or the consummation of Contemplated

Transactions. Prior to the date hereof, Parent has provided or otherwise made available to the Company true and correct copies of all material environmental reports, assessments, studies and audits in the possession or control of Parent with respect to any property leased or controlled by Parent or any business operated by it.

3.19 **Insurance**. Parent has delivered or made available to the Company accurate and complete copies of all material insurance policies and all material self-insurance programs and arrangements relating to the business, assets, liabilities and operations of Parent. Each of such insurance policies is in full force and effect and Parent is in compliance in all material respects with the terms thereof. Other than customary end of policy notifications from insurance carriers, since January 1, 2016, Parent has not received any notice or other communication regarding any actual or possible: (a) cancellation or invalidation of any insurance policy; or (b) refusal or denial of any coverage, reservation of rights or rejection of any material claim under any insurance policy. Parent has provided timely written notice to the appropriate insurance carrier(s) of each Legal Proceeding that is currently pending against Parent for which Parent has insurance coverage, and no such carrier has issued a denial of coverage or a reservation of rights with respect to any such Legal Proceeding, or informed Parent of its intent to do so.

3.20 **No Financial Advisors**. No broker, finder or investment banker is entitled to any brokerage fee, finder's fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of Parent.

3.21 **Transactions with Affiliates**. Except as set forth in the Parent SEC Documents filed prior to the date of this Agreement, since the date of Parent's last proxy statement filed in 2019 with the SEC, no event has occurred that would be required to be reported by Parent pursuant to Item 404 of Regulation S-K. Section 3.21 of the Parent Disclosure Schedule identifies each Person who is (or who may be deemed to be) an Affiliate of Parent as of the date of this Agreement.

3.22 **Anti-Bribery**. Neither Parent nor any of its directors, officers, employees or, to Parent's Knowledge, agents or any other Person acting on its behalf has directly or indirectly made any bribes, rebates, payoffs, influence payments, kickbacks, illegal payments, illegal political contributions, or other payments, in the form of cash, gifts, or otherwise, or taken any other action, in violation of Anti-Bribery Laws. To the Knowledge of Parent, Parent is not or has not been the subject of any investigation or inquiry by any Governmental Body with respect to potential violations of Anti-Bribery Laws.

3.23 **Valid Issuance**. The Parent Common Stock to be issued in the Merger will, when issued in accordance with the provisions of this Agreement, be validly issued, fully paid and nonassessable.

3.24 **Opinion of Financial Advisor**. The Parent Board has received an opinion of Stifel, Nicolaus & Company, Incorporated to the effect that, as of the date of this Agreement and subject to the assumptions, qualifications, limitations and other matters set forth therein that the Consideration to be paid by Parent in the Merger pursuant to this Agreement is fair, from a financial point of view, to Parent. It is agreed and understood that such opinion is for the benefit of the Parent Board and may not be relied upon by the Company or any other party.

3.25 **Disclaimer of Other Representations or Warranties**.

(a) Except as previously set forth in this Section 3 or in any certificate delivered by Parent or Merger Sub to the Company pursuant to this Agreement, neither Parent nor Merger Sub makes any representation or warranty, express or implied, at law or in equity, with respect to it or any of its assets, liabilities or operations, and any such other representations or warranties are hereby expressly disclaimed.

(b) Each of Parent and Merger Sub acknowledges and agrees that, except for the representations and warranties of the Company set forth in Section 2, none of Parent, Merger Sub or any of their respective Representatives is relying on any other representation or warranty of the Company or any other Person made outside of Section 2, including regarding the accuracy or completeness of any such other representations or warranties or the omission of any material information, whether express or implied, in each case, with respect to the Contemplated Transactions.

Section 4. CERTAIN COVENANTS OF THE PARTIES

4.1 **Operation of Parent's Business**.

(a) Except as set forth on Section 4.1(a) of the Parent Disclosure Schedule, as expressly permitted by this Agreement, as required by applicable Law or unless the Company shall otherwise consent in writing (which consent shall not be unreasonably withheld, delayed or conditioned), during the period commencing on the date of this Agreement and continuing until the earlier to occur of the termination of this Agreement pursuant to Section 9 and the Effective Time (the "***Pre-Closing Period***"), each of Parent and Merger Sub shall conduct its business and operations in the Ordinary Course of Business and in compliance in all material respects with all applicable Laws and the requirements of all Contracts that constitute Parent Material Contracts, shall keep in full force and effect all material insurance policies of Parent and shall not take any action that would materially adversely affect or delay the ability of any of the parties hereto from obtaining any necessary approvals required by this Agreement, performing its covenants or agreements hereunder, or otherwise materially delay or prohibit the Contemplated Transactions.

(b) Except (i) as expressly permitted by this Agreement, (ii) as set forth in Section 4.1(b) of the Parent Disclosure Schedule, (iii) as required by applicable Law or (iv) with the prior written consent of the Company (which consent shall not be unreasonably withheld, delayed or conditioned), at all times during the Pre-Closing Period, Parent shall not, nor shall it cause or permit Merger Sub to, do any of the following:

(i) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except in connection with the payment of the exercise price and/or withholding Taxes incurred upon the exercise, settlement or vesting of any award granted under the Parent Stock Plans in accordance with the terms of such award in effect on the date of this Agreement);

(ii) sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of Parent (except for Parent Common Stock issued upon the valid exercise of outstanding Parent Options); (B) any option, warrant or right to acquire any capital stock or any other security, other than option grants to employees and service providers in the Ordinary Course of Business; or (C) any other instrument convertible into or exchangeable for any capital stock or other security of Parent;

(iii) except as required to give effect to anything in contemplation of the Closing, amend any of its Organizational Documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, the Contemplated Transactions;

(iv) form any Subsidiary or acquire any equity interest or other interest in any other Entity or enter into a joint venture with any other Entity;

(v) (A) lend money to any Person (except for the advance of reasonable expenses to employees, directors and consultants in the Ordinary Course of Business), (B) incur or guarantee any indebtedness for borrowed money or (C) guarantee any debt securities of others;

(vi) other than as required by applicable Law or the terms of any Parent Benefit Plan as in effect on the date of this Agreement: (A) adopt, terminate, establish or enter into any Parent Benefit Plan; (B) cause or permit any Parent Benefit Plan to be amended in any material respect; (C) pay any bonus or make any profit-sharing or similar payment to, or increase the amount of the wages, salary, commissions, benefits or other compensation or remuneration payable to, any of its directors, officers or employees, other than increases in base salary and annual cash bonus opportunities and payments made in the Ordinary Course of Business consistent with past practice; or (D) increase the severance, retention or change of control benefits offered to any current or former or new employees, directors or consultants;

(vii) recognize any labor union, labor organization, or similar Person except as otherwise required by law and after advance notice to the Company;

(viii) enter into any material transaction other than in the Ordinary Course of Business;

(ix) acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any Encumbrance with respect to such assets or properties;

(x) sell, assign, transfer, license, sublicense or otherwise dispose of any material Parent IP (other than pursuant to non-exclusive licenses in the Ordinary Course of Business);

(xi) make, change or revoke any material Tax election, fail to pay any income or other material Tax as such Tax becomes due and payable, file any amendment making any material change to any Tax Return, settle or compromise any income or other material Tax liability, enter into any Tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes), request or Consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material Taxes (other than pursuant to an extension of time to file any Tax Return granted in the Ordinary Course of Business of not more than six months), or adopt or change any material accounting method in respect of Taxes;

(xii) enter into, materially amend or terminate any Parent Material Contract;

(xiii) other than incurrence or payment of Parent Transaction Expenses, make any expenditures, incur any Liabilities or discharge or satisfy any Liabilities, in each case, outside of the Ordinary Course of Business;

(xiv) other than as required by Law or GAAP, take any action to change accounting policies or procedures;

(xv) initiate or settle any Legal Proceeding; or

(xvi) agree, resolve or commit to do any of the foregoing.

Nothing contained in this Agreement shall give the Company, directly or indirectly, the right to control or direct the operations of Parent prior to the Effective Time. Prior to the Effective Time, Parent shall exercise, consistent with the terms and conditions of this Agreement, complete unilateral control and supervision over its business operations.

4.2 **Operation of the Company's Business**.

(a) Except as set forth on Section 4.2(a) of the Company Disclosure Schedule, as expressly permitted by this Agreement, as required by applicable Law or unless Parent shall otherwise consent in writing (which consent shall not be unreasonably withheld, delayed or conditioned), during the Pre-Closing Period: the Company shall conduct its business and operations in the Ordinary Course of Business and in compliance in all material respects with all applicable Laws and the requirements of all Contracts that constitute Company Material Contracts, shall keep in full force and effect all material insurance policies of the Company and shall not take any action that would materially adversely affect or delay the ability of any of the parties hereto from obtaining any necessary approvals required by this Agreement, performing its covenants or agreements hereunder, or otherwise materially delay or prohibit the Contemplated Transactions.

(b) Except (i) as expressly permitted by this Agreement, (ii) as set forth in Section 4.2(b) of the Company Disclosure Schedule, (iii) as required by applicable Law or (iv) with the prior written consent of Parent (which consent shall not be unreasonably withheld, delayed or conditioned), at all times during the Pre-Closing Period, the Company shall not do any of the following:

(i) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except for shares of Company Common Stock from terminated employees, directors or consultants of the Company);

(ii) sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of the Company (except for shares of outstanding Company Common Stock issued upon the valid exercise of Company Options); (B) any

option, warrant or right to acquire any capital stock or any other security, other than option grants to employees and service providers in the Ordinary Course of Business; or (C) any other instrument convertible into or exchangeable for any capital stock or other security of the Company;

(iii) except as required to give effect to anything in contemplation of the Closing, amend its Organizational Documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, the Contemplated Transactions;

(iv) form any Subsidiary or acquire any equity interest or other interest in any other Entity or enter into a joint venture with any other Entity;

(v) (A) lend money to any Person (except for the advance of reasonable expenses to employees, directors and consultants in the Ordinary Course of Business), (B) incur or guarantee any indebtedness for borrowed money or (C) guarantee any debt securities of others;

(vi) other than as required by applicable Law or the terms of any Company Benefit Plan as in effect on the date of this Agreement: (A) adopt, terminate, establish or enter into any Company Benefit Plan; (B) cause or permit any Company Benefit Plan to be amended in any material respect; (C) pay any bonus or make any profit-sharing or similar payment to, or increase the amount of the wages, salary, commissions, benefits or other compensation or remuneration payable to, any of its directors, officers or employees, other than increases in base salary and annual cash bonus opportunities and payments made in the Ordinary Course of Business consistent with past practice; or (D) increase the severance, retention or change of control benefits offered to any current or former or new employees, directors or consultants;

(vii) recognize any labor union, labor organization, or similar Person, except as otherwise required by law and after advance notice to the Parent;

(viii) enter into any material transaction other than in the Ordinary Course of Business;

(ix) acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any Encumbrance with respect to such assets or properties;

(x) sell, assign, transfer, license, sublicense or otherwise dispose of any material Company IP (other than pursuant to non-exclusive licenses in the Ordinary Course of Business);

(xi) make, change or revoke any material Tax election, fail to pay any income or other material Tax as such Tax becomes due and payable, file any amendment making any material change to any Tax Return, settle or compromise any income or other material Tax liability, enter into any Tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes), request or Consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material Taxes (other than pursuant to an extension of time to file any Tax Return granted in the Ordinary Course of Business of not more than six months), or adopt or change any material accounting method in respect of Taxes;

(xii) enter into, materially amend or terminate any Company Material Contract;

(xiii) other than incurrence or payment of any Company Transaction Expenses, make any expenditures, incur any Liabilities or discharge or satisfy any Liabilities, in each case, outside of the Ordinary Course of Business;

(xiv) other than as required by Law or GAAP, take any action to change accounting policies or procedures;

(xv) initiate or settle any Legal Proceeding; or

(xvi) agree, resolve or commit to do any of the foregoing.

(c) Nothing contained in this Agreement shall give Parent, directly or indirectly, the right to control or direct the operations of the Company prior to the Effective Time. Prior to the Effective Time, the Company shall exercise, consistent with the terms and conditions of this Agreement, complete unilateral control and supervision over its business operations.

4.3 **Access and Investigation**.

(a) Subject to the terms of the Confidentiality Agreement, which the Parties agree will continue in full force following the date of this Agreement, during the Pre-Closing Period, upon reasonable notice, Parent, on the one hand, and the Company, on the other hand, shall and shall use commercially reasonable efforts to cause such Party's Representatives to: (i) provide the other Party and such other Party's Representatives with reasonable access during normal business hours to such Party's Representatives, personnel, property and assets and to all existing books, records, Tax Returns, work papers and other documents and information relating to such Party and its Subsidiaries; (ii) provide the other Party and such other Party's Representatives with such copies of the existing books, records, Tax Returns, work papers, product data, and other documents and information relating to such Party and its Subsidiaries, and with such additional financial, operating and other data and information regarding such Party and its Subsidiaries as the other Party may reasonably request; (iii) permit the other Party's officers and other employees to meet, upon reasonable notice and during normal business hours, with the chief financial officer and other officers and managers of such Party responsible for such Party's financial statements and the internal controls of such Party to discuss such matters as the other Party may deem necessary or appropriate; and (iv) make available to the other Party copies of unaudited financial statements, material operating and financial reports prepared for senior management or the board of directors of such Party, and any material notice, report or other document filed with or sent to or received from any Governmental Body in connection with the Contemplated Transactions. Any investigation conducted by either Parent or the Company pursuant to this Section 4.3 shall be conducted in such manner as not to interfere unreasonably with the conduct of the business of the other Party.

(b) Notwithstanding the foregoing, any Party may restrict the foregoing access to the extent that any Law applicable to such Party requires such Party to restrict or prohibit access to any such properties or information or, if in the reasonable judgment of such Party, access would jeopardize protections afforded the Party under the attorney-client privilege or the attorney work product doctrine; *provided*, *however*, that such Party shall use commercially reasonable efforts to allow for such access in a manner that does not violate any such applicable Law or jeopardize protections afforded the Party under the attorney-client privilege or the attorney work product doctrine.

4.4 **Parent Non-Solicitation**.

(a) Parent agrees that, during the Pre-Closing Period, it shall not, and shall cause its Representatives not to, directly or indirectly: (i) solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of any Acquisition Proposal or Acquisition Inquiry or take any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (ii) furnish any non-public information regarding Parent to any Person in connection with or in response to an Acquisition Proposal or Acquisition Inquiry; (iii) engage in discussions or negotiations with any Person with respect to any Acquisition Proposal or Acquisition Inquiry; (iv) approve, endorse or recommend any Acquisition Proposal (subject to Section 5.3); (v) execute or enter into any letter of intent or any Contract contemplating or otherwise relating to any Acquisition Transaction (other than a confidentiality agreement permitted under this Section 4.4(a)); or (vi) publicly propose to do any of the foregoing; *provided*, *however*, that, notwithstanding anything contained in this Section 4.4 and subject to compliance with this Section 4.4, prior to obtaining the Required Parent Stockholder Vote, Parent may furnish non-public information regarding Parent to, and enter into discussions or negotiations with, any Person in response to an unsolicited *bona fide* Acquisition Proposal by such Person, which the Parent Board determines in good faith, after consultation with Parent's outside financial advisors and outside legal counsel, constitutes, or is reasonably likely to result in, a Superior Offer (and is not withdrawn) if: (A) neither Parent nor any of its Representatives shall have breached this Section 4.4 in any material respect, (B) the Parent Board concludes in good faith based on the advice of outside legal counsel, that the failure to take such action is reasonably likely to be inconsistent with the fiduciary duties of the Parent Board under applicable Law; (C) at least two (2) Business Days prior to furnishing such nonpublic

confidential information to, or entering into discussions with, such Person, Parent gives the Company written notice of the identity of such Person and of Parent's intention to furnish nonpublic information to, or enter into discussions with, such Person; (D) Parent receives from such Person an executed confidentiality agreement containing provisions, in the aggregate, at least as favorable to Parent as those contained in the Confidentiality Agreement; and (E) at least two (2) Business Days prior to furnishing any such nonpublic information to such Person, Parent furnishes such nonpublic information to the Company (to the extent such information has not been previously furnished by Parent to the Company). Without limiting the generality of the foregoing, Parent acknowledges and agrees that, in the event any Representative of Parent (whether or not such Representative is purporting to act on behalf of Parent) takes any action that, if taken by Parent, would constitute a breach of this Section 4.4, the taking of such action by such Representative shall be deemed to constitute a breach of this Section 4.4 by Parent for purposes of this Agreement.

(b) If Parent or any Representative of Parent receives an Acquisition Proposal or Acquisition Inquiry at any time during the Pre-Closing Period, then Parent shall promptly (and in no event later than twenty-four (24) hours after Parent becomes aware of such Acquisition Proposal or Acquisition Inquiry) advise the Company orally and in writing of such Acquisition Proposal or Acquisition Inquiry (including the identity of the Person making or submitting such Acquisition Proposal or Acquisition Inquiry, and the material terms thereof). Parent shall keep the Company reasonably informed with respect to the status and material terms of any such Acquisition Proposal or Acquisition Inquiry and promptly (and in no event later than twenty-four (24) hours) advise the Company orally and in writing of any material modification or proposed material modification thereto.

(c) Parent shall immediately cease and cause to be terminated any existing discussions, negotiations and communications with any Person that relate to any Acquisition Proposal or Acquisition Inquiry as of the date of this Agreement.

4.5 **Company Non-Solicitation**.

(a) The Company agrees that, during the Pre-Closing Period, it shall cause its Representatives not to, directly or indirectly: (i) solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of any Acquisition Proposal or Acquisition Inquiry or take any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (ii) furnish any non-public information regarding the Company to any Person in connection with or in response to an Acquisition Proposal or Acquisition Inquiry; (iii) engage in discussions or negotiations with any Person with respect to any Acquisition Proposal or Acquisition Inquiry; (iv) approve, endorse or recommend any Acquisition Proposal; (v) execute or enter into any letter of intent or any Contract contemplating or otherwise relating to any Acquisition Transaction; or (vi) publicly propose to do any of the foregoing; *provided*, *however*, that, notwithstanding anything contained in this Section 4.5 and subject to compliance with this Section 4.5, prior to obtaining the Required Company Stockholder Vote, the Company may furnish non-public information regarding the Company to, and enter into discussions or negotiations with, any Person in response to an unsolicited *bona fide* Acquisition Proposal by such Person, which the Company Board determines in good faith, after consultation with the Company's outside financial advisors and outside legal counsel, constitutes, or is reasonably likely to result in, a Superior Offer (and is not withdrawn) if: (A) neither the Company nor any of its Representatives shall have breached this Section 4.5 in any material respect, (B) the Company Board concludes in good faith based on the advice of outside legal counsel, that the failure to take such action is reasonably likely to be inconsistent with the fiduciary duties of the Company Board under applicable Law; (C) at least two (2) Business Days prior to furnishing such nonpublic confidential information to, or entering into discussions with, such Person, the Company gives Parent written notice of the identity of such Person and of the Company's intention to furnish nonpublic information to, or enter into discussions with, such Person; (D) the Company receives from such Person an executed confidentiality agreement containing provisions, in the aggregate, at least as favorable to the Company as those contained in the Confidentiality Agreement; and (E) at least two (2) Business Days prior to furnishing any such nonpublic information to such Person, the Company furnishes such nonpublic information to Parent (to the extent such information has not been previously furnished by the Company to Parent). Without limiting the generality of the foregoing, the Company acknowledges and agrees that, in the event any Representative of the Company (whether or not such Representative is purporting to act

on behalf of the Company) takes any action that, if taken by the Company, would constitute a breach of this Section 4.5, the taking of such action by such Representative shall be deemed to constitute a breach of this Section 4.5 by the Company for purposes of this Agreement.

(b) If the Company or any Representative of the Company receives an Acquisition Proposal or Acquisition Inquiry at any time during the Pre-Closing Period, then the Company shall promptly (and in no event later than twenty-four (24) hours after the Company becomes aware of such Acquisition Proposal or Acquisition Inquiry) advise Parent orally and in writing of such Acquisition Proposal or Acquisition Inquiry (including the identity of the Person making or submitting such Acquisition Proposal or Acquisition Inquiry, and the material terms thereof). The Company shall keep Parent reasonably informed with respect to the status and material terms of any such Acquisition Proposal or Acquisition Inquiry and promptly (and in no event later than twenty-four (24) hours) advise the Company orally and in writing of any material modification or proposed material modification thereto.

(c) The Company shall immediately cease and cause to be terminated any existing discussions, negotiations and communications with any Person that relate to any Acquisition Proposal or Acquisition Inquiry as of the date of this Agreement.

4.6 **Notification of Certain Matters**.

(a) During the Pre-Closing Period, the Company shall promptly notify Parent (and, if in writing, furnish copies of) if any of the following occurs: (i) any notice or other communication is received from any Person alleging that the Consent of such Person is or may be required in connection with any of the Contemplated Transactions; (ii) any Legal Proceeding against or involving or otherwise affecting the Company is commenced, or, to the Knowledge of the Company, threatened against the Company or, to the Knowledge of the Company, any director or officer of the Company; (iii) the Company becomes aware of any inaccuracy in any representation or warranty made by it in this Agreement; or (iv) the failure of the Company to comply with any covenant or obligation of the Company; in the case of (iii) and (iv) that could reasonably be expected to make the timely satisfaction of any of the conditions set forth in Sections 6 or 7, as applicable, impossible or materially less likely. No notification given to Parent pursuant to this Section 4.6(a) shall change, limit or otherwise affect any of the representations, warranties, covenants or obligations of the Company contained in this Agreement or the Company Disclosure Schedule for purposes of Sections 6 and 7, as applicable. Notwithstanding the foregoing, as long as the failure to give such notice does not materially and adversely prejudice the ability of Parent to terminate this Agreement pursuant to Section 9.1(g), the failure to give any such notice shall not be treated as a breach of covenant for purposes of Section 7.2.

(b) During the Pre-Closing Period, Parent shall promptly notify the Company (and, if in writing, furnish copies of) if any of the following occurs: (i) any notice or other communication is received from any Person alleging that the Consent of such Person is or may be required in connection with any of the Contemplated Transactions; (ii) any Legal Proceeding against or involving or otherwise affecting Parent is commenced, or, to the Knowledge of Parent, threatened against Parent or, to the Knowledge of Parent, any director or officer of Parent; (iii) Parent becomes aware of any inaccuracy in any representation or warranty made by it in this Agreement; or (iv) the failure of Parent to comply with any covenant or obligation of Parent or Merger Sub; in the case of (iii) and (iv) that could reasonably be expected to make the timely satisfaction of any of the conditions set forth in Sections 6 or 8, as applicable, impossible or materially less likely. No notification given to the Company pursuant to this Section 4.6(b) shall change, limit or otherwise affect any of the representations, warranties, covenants or obligations of Parent contained in this Agreement or the Parent Disclosure Schedule for purposes of Sections 6 and8, as applicable. Notwithstanding the foregoing, as long as the failure to give such notice does not materially and adversely prejudice the ability of the Company to terminate this Agreement pursuant to Section 9.1(f), the failure to give any such notice shall not be treated as a breach of covenant for purposes of Section 8.2.

4.7 **Offers to Employees**.

(a) Each current employee of Parent, the Company, or any Affiliate thereof who continues employment with Parent, the Company, or any Affiliate thereof after the Effective Time will be a "***Continuing Employee***." For the avoidance of doubt, each current employee of the Company shall be offered the opportunity to continue employment with Parent, the Company, or any Affiliate thereof after the Effective Time. During the period beginning as of the Effective Time and ending no earlier than the first (1st) anniversary of the Effective Time, Parent shall provide each Continuing Employee with, or cause each Continuing Employee to receive, (i) at least the same level of base wages or base salary (but excluding incentive compensation and equity-based compensation opportunities) that were provided to the Continuing Employee immediately prior to the Effective Time and (ii) employee benefits that are substantially similar in the aggregate to the employee benefits that were provided to the Continuing Employee immediately prior to the Closing.

(b) Parent shall, and shall cause its Affiliates to, grant all Continuing Employees credit for any service to the Company and its Affiliates earned prior to the Closing for purposes of eligibility, vesting and determination of the level of benefits, vacation or paid time off accrual and severance benefit determinations, under any benefit or compensation plan, program, agreement or arrangement in which a Continuing Employee participates that may be established or maintained by Parent or its Affiliates on or after the Closing (the "***New Plans***"); provided, however, that such service credit shall not be recognized to the extent that it would result in a duplication of benefits for the same period of time. In addition, Parent shall, and shall cause its Affiliates to, cause (i) to be waived all pre-existing condition exclusions and actively-at-work requirements and similar limitations, eligibility waiting periods and evidence of insurability requirements under any New Plans to the extent waived or satisfied by a Continuing Employee under any Company Benefit Plan as of the Closing and (ii) any deductible, co-insurance and covered out-of-pocket expenses paid on or before the Closing by any Continuing Employee (or covered dependent thereof) to be taken into account for purposes of satisfying the corresponding deductible, coinsurance and maximum out-of-pocket provisions after the Closing under any applicable New Plan in the same plan year in which the Closing occurs.

(c) Nothing contained herein, express or implied, (i) is intended to confer upon any Continuing Employee any right to continued employment for any period or continued receipt of any specific employee benefit, or shall constitute an amendment to or any other modification of any benefit plan, (ii) shall alter or limit Parent's or the Company's or their Affiliates' ability to amend, modify or terminate any particular benefit plan, program, agreement or arrangement or (iii) is intended to confer upon any individual (including employees, retirees or dependents or beneficiaries of employees or retirees) any right as a third party beneficiary of this Agreement.

Section 5. ADDITIONAL AGREEMENTS OF THE PARTIES

5.1 **Proxy Statement**.

(a) As promptly as practicable after the date of this Agreement (but in no event later than forty-five (45) days following the date of this Agreement), the Parties shall prepare and cause to be filed with the SEC a preliminary Proxy Statement. Following (i) confirmation by the SEC that it has no further comments or (ii) expiration of the 10-day waiting period contemplated by Rule 14a-6(a) promulgated under the Exchange Act, Parent shall use commercially reasonable efforts to cause the Proxy Statement in definitive form to be mailed to the stockholders of Parent.

(b) Parent covenants and agrees that the information provided by Parent or its Subsidiaries to the Company for inclusion in the Proxy Statement, including any pro forma financial statements included therein (and the letter to stockholders, notice of meeting and form of proxy included therewith), will not, at the time that the Proxy Statement or any amendment or supplement thereto is filed with the SEC or is first mailed to the Parent stockholders contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading.

(c) The Company represents, covenants and agrees that the information provided by the Company to Parent for inclusion in the Proxy Statement (including the Company Financials) will not contain any

untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make such information not misleading. Notwithstanding the foregoing, (i) Parent makes no covenant, representation or warranty with respect to statements made in the Proxy Statement (and the letter to stockholders, notice of meeting and form of proxy included therewith), if any, based on information provided by the Company or any of its Representatives specifically for inclusion therein and (ii) the Company makes no covenant, representation or warranty with respect to statements made in the Proxy Statement (and the letter to stockholders, notice of meeting and form of proxy included therewith), if any, other than with respect to the information provided by the Company or any of its Representatives for inclusion therein.

(d) Each of the Parties shall use commercially reasonable efforts to cause the Proxy Statement to comply with the applicable rules and regulations promulgated by the SEC and to respond promptly to any comments of the SEC or its staff. Each Party shall promptly furnish to the other Party all information concerning such Party and such Party's Affiliates and such Party's stockholders that may be required or reasonably requested in connection with any action contemplated by this Section 5.1. If Parent, Merger Sub or the Company become aware of any event or information that, pursuant to the Securities Act or the Exchange Act, should be disclosed in an amendment or supplement to the Proxy Statement, as the case may be, then such Party, as the case may be, shall promptly inform the other Parties thereof and shall cooperate with such other Parties in filing such amendment or supplement with the SEC and, if appropriate, in mailing such amendment or supplement to the Parent stockholders.

(e) In furtherance of the foregoing, the Company shall reasonably cooperate with Parent and provide, and require its Representatives, advisors, accountants and attorneys to provide, Parent and its Representatives, advisors, accountants and attorneys, with all true, correct and complete information regarding Company that is required by Law to be included in the Proxy Statement or reasonably requested from Company to be included in the Proxy Statement. Without limiting the foregoing, the Company will use commercially reasonable efforts to cause the Company's independent accounting firm to deliver any auditor's report and any other documentation required by Law to be included in the Proxy Statement.

5.2 **Company Stockholder Matters**. Promptly following receipt of the Required Company Stockholder Vote, the Company shall prepare and mail a notice (the "***Stockholder Notice***") to every stockholder of the Company that did not execute the Company Stockholder Written Consent. The Stockholder Notice shall (i) be a statement to the effect that the Company Board determined that the Merger is advisable in accordance with Section 251(b) of the DGCL and in the best interests of the stockholders of the Company and approved and adopted this Agreement, the Merger and the other Contemplated Transactions, (ii) provide the stockholders of the Company to whom it is sent with notice of the actions taken in the Company Stockholder Written Consent, including the adoption and approval of this Agreement, the Merger and the other Contemplated Transactions in accordance with Section 228(e) of the DGCL and the certificate of incorporation and bylaws of the Company and (iii) include a description of the appraisal rights of the Company's stockholders available under the DGCL, along with such other information as is required thereunder and pursuant to applicable Law. All materials (including any amendments thereto) submitted to the stockholders of the Company in accordance with this Section 5.2 shall be subject to Parent's advance review and reasonable approval.

5.3 **Parent Stockholders' Meeting**.

(a) As promptly as practicable following the earlier to occur of (i) confirmation by the SEC that it has no further comments on the preliminary Proxy Statement or (ii) expiration of the 10-day waiting period contemplated by Rule 14a-6(a) promulgated under the Exchange Act, Parent shall take all action necessary under applicable Law to call, give notice of and hold a meeting of the holders of Parent Common Stock for the purpose of seeking approval of:

(i) the amendment of Parent's certificate of incorporation to effect the Nasdaq Reverse Split;

(ii) the issuance of shares of Parent Common Stock to the Company's stockholders in connection with the Contemplated Transactions;

(iii) the change of control of Parent resulting from the Merger pursuant to the Nasdaq rules, if required; and

(iv) in accordance with Section 14A of the Exchange Act and the applicable SEC rules issued thereunder, seeking advisory approval of a proposal to the Parent's stockholders for a non-binding, advisory vote to approve certain compensation that may become payable to Parent's named executed officers in connection with the completion of the Merger, if applicable (the matters contemplated by the clauses 5.3(a)(i) – (iii) are referred to as the "***Parent Stockholder Matters***," and the matters contemplated by clause 5.3(a)(iv) is referred to herein as the "***Other Parent Stockholder Matters***," and such meeting, the "***Parent Stockholders' Meeting***").

(b) The Parent Stockholders' Meeting shall be held as promptly as practicable, and in any event within 60 days, following the earlier to occur of (A) confirmation by the SEC that it has no further comments or (B) expiration of the 10-day waiting period contemplated by Rule 14a-6(a) promulgated under the Exchange Act with respect to the filing of the preliminary Proxy Statement. Notwithstanding anything to the contrary contained herein, if on the date of the Parent Stockholders' Meeting or on a date preceding the date on which or the date on which the Parent Stockholders' Meeting is scheduled, Parent reasonably believes that (A) it will not receive proxies sufficient to obtain the Parent Stockholder Approval, whether or not a quorum would be present or (B) it will not have sufficient shares of Parent Common Stock represented (either in Person or by proxy) to constitute a quorum necessary to conduct the business of the Parent Stockholders' Meeting, Parent may, after reasonable consultation with the Company, postpone or adjourn, or make one or more successive postponements or adjournments of, the Parent Stockholders' Meeting as long as the date of the Parent Stockholders' Meeting is not postponed or adjourned more than an aggregate of 60 calendar days in connection with any postponements or adjournments in reliance on the preceding sentence.

(c) Parent agrees that, subject to Section 5.3(d): (i) the Parent Board shall recommend that the holders of Parent Common Stock vote to approve the Parent Stockholder Matters and shall use reasonable best efforts to solicit such approval; (ii) the Proxy Statement shall include a statement to the effect that the Parent Board recommends that Parent's stockholders vote to approve the Parent Stockholder Matters (the recommendation of the Parent Board with respect to the Parent Stockholder Matters being referred to as the "***Parent Board Recommendation***"); (iii) the Parent Board Recommendation shall not be withheld, amended, withdrawn, qualified or modified (and the Parent Board shall not publicly propose to withhold, amend, withdraw, qualify or modify the Parent Board Recommendation) in a manner adverse to the Company; and (iv) the Parent Board shall not fail to recommend, in a solicitation/recommendation statement on Schedule 14D-9, against any Acquisition Proposal or Acquisition Transaction subject to Regulation 14D promulgated under the Exchange Act (other than any other tender offer or exchange offer by Parent or Merger Sub) within ten (10) Business Days after the commencement (within the meaning of Rule 14d-2 under the Exchange Act) of such Acquisition Proposal or Acquisition Transaction (the actions set forth in the foregoing clauses (iii) and (iv), collectively, a "***Parent Board Adverse Recommendation Change***").

(d) Notwithstanding anything to the contrary contained in this Agreement, if at any time prior to the approval of Parent Stockholder Matters by the Required Parent Stockholder Vote:

(i) if Parent has received a written Acquisition Proposal (which Acquisition Proposal did not arise out of a breach of Section 4.4 (other than *de minimis* violations)) from any Person that has not been withdrawn and after consultation with outside legal counsel, the Parent Board shall have determined, in good faith, that such Acquisition Proposal is a Superior Offer, the Parent Board may make a Parent Board Adverse Recommendation Change, if and only if: (A) the Parent Board determines in good faith, after consultation with Parent's outside legal counsel, that the failure to do so could be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law; (B) Parent shall have given the Company prior written notice of its intention to consider making a Parent Board Adverse Recommendation Change at least four (4) Business Days prior to making any such Parent Board Adverse Recommendation Change (a "***Determination Notice***") (which notice shall not constitute a Parent Board Adverse Recommendation Change); and (C) (1) Parent shall have provided to the Company a summary of the material terms and conditions of the Acquisition Proposal in accordance with Section 4.4(b), (2) Parent shall have given the Company four Business Days after the Determination Notice to propose revisions to the terms of this Agreement or make another proposal and shall have made its Representatives reasonably available to

negotiate in good faith with the Company (to the extent the Company desires to negotiate) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by the Company, if any, after consultation with outside legal counsel, the Parent Board shall have determined, in good faith, that such Acquisition Proposal is a Superior Offer and that the failure to make the Parent Board Adverse Recommendation Change could be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law. For the avoidance of doubt, the provisions of this Section 5.3(d)(i) shall also apply to any material change to the facts and circumstances relating to such Acquisition Proposal and require a new Determination Notice, except that the references to four Business Days shall be deemed to be three Business Days.

(ii) Other than in connection with an Acquisition Proposal, the Parent Board may make a Parent Board Adverse Recommendation Change in response to a Parent Change in Circumstance, if and only if: (A) the Parent Board determines in good faith, after consultation with Parent's outside legal counsel, that the failure to do so could be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law; (B) Parent shall have given the Company a Determination Notice at least four Business Days prior to making any such Parent Board Adverse Recommendation Change; and (C) (1) Parent shall have specified the Parent Change in Circumstance in reasonable detail, (2) Parent shall have given the Company four Business Days after the Determination Notice to propose revisions to the terms of this Agreement or make another proposal, and shall have made its Representatives reasonably available to negotiate in good faith with the Company (to the extent the Company desires to do so) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by the Company, if any, after consultation with outside legal counsel, the Parent Board shall have determined, in good faith, that the failure to make the Parent Board Adverse Recommendation Change in response to such Parent Change in Circumstance could be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law. For the avoidance of doubt, the provisions of this Section 5.3(d)(ii) shall also apply to any material change to the facts and circumstances relating to such Parent Change in Circumstance and require a new Determination Notice, except that the references to four Business Days shall be deemed to be three Business Days.

(e) Nothing contained in this Agreement shall prohibit Parent or the Parent Board from (i) complying with Rules 14d-9 and 14e-2(a) promulgated under the Exchange Act, (ii) issuing a "stop, look and listen" communication or similar communication of the type contemplated by Section 14d-9(f) under the Exchange Act or (iii) otherwise making any disclosure to the Parent stockholders; *provided, however*, that in the case of the foregoing clause (iii) the Parent Board determines in good faith, after consultation with its outside legal counsel, that failure to make such disclosure is reasonably likely to be inconsistent with applicable Law, including its fiduciary duties under applicable Law.

5.4 **Company Options**.

(a) At the Effective Time, each Company Option that is outstanding and unexercised immediately prior to the Effective Time under the Company Plan, whether or not vested, shall be converted into and become an option to purchase Parent Common Stock, and Parent shall assume each such Company Option in accordance with the terms (as in effect as of the date of this Agreement) of the Company Plan and the terms of the stock option agreement by which such Company Option is evidenced (but with changes to such documents as Parent and the Company mutually agree are appropriate to reflect the substitution of the Company Options by Parent to purchase shares of Parent Common Stock). All rights with respect to Company Common Stock under Company Options assumed by Parent shall thereupon be converted into rights with respect to Parent Common Stock. Accordingly, from and after the Effective Time: (i) each Company Option assumed by Parent may be exercised solely for shares of Parent Common Stock; (ii) the number of shares of Parent Common Stock subject to each Company Option assumed by Parent shall be determined by multiplying (A) the number of shares of Company Common Stock that were subject to such Company Option, as in effect immediately prior to the Effective Time, by (B) the Per Share Common Stock Exchange Ratio (as defined in the Company Charter Amendment), and rounding the resulting number down to the nearest whole number of shares of Parent Common Stock; (iii) the per share exercise price for the

Parent Common Stock issuable upon exercise of each Company Option assumed by Parent shall be determined by dividing (A) the per share exercise price of Company Common Stock subject to such Company Option, as in effect immediately prior to the Effective Time, by (B) the Per Share Common Stock Exchange Ratio (as defined in the Company Charter Amendment) and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on the exercise of any Company Option assumed by Parent shall continue in full force and effect and the term, exercisability, vesting schedule and other provisions of such Company Option shall otherwise remain unchanged; *provided*, *however*, that: (A) to the extent provided under the terms of a Company Option and the Company Plans, such Company Option may be further adjusted as necessary to reflect Parent's substitution of the Company Options with options to purchase Parent Common Stock (such as by making any change in control or similar definition relate to Parent and having any provision that provides for the adjustment of Company Options upon the occurrence of certain corporate events relate to corporate events that relate to Parent and/or Parent Common Stock); and (B) the Parent Board or an authorized committee thereof shall succeed to the authority and responsibility of the Company Board or any committee thereof with respect to each Company Option assumed by Parent. Notwithstanding anything to the contrary in this Section 5.4(a), the conversion of each Company Option (regardless of whether such option qualifies as an "incentive stock option" within the meaning of Section 422 of the Code) into an option to purchase shares of Parent Common Stock shall be made in a manner consistent with Treasury Regulation Section 1.424-1, such that the conversion of a Company Option shall not constitute a "modification" of such Company Option for purposes of Section 409A or Section 424 of the Code.

(b) Parent shall file with the SEC, promptly after the Effective Time and in any case no later than 20 days after the Closing, a registration statement on Form S-8 (or any successor or alternative form), relating to the shares of Parent Common Stock issuable with respect to Company Options assumed by Parent in accordance with Section 5.4(a) unless such shares of Parent Common Stock have otherwise already been registered.

(c) Prior to the Effective Time, the Company shall take all actions that may be necessary (under the Company Plan and otherwise) to effectuate the provisions of this Section 5.4 and to ensure that, from and after the Effective Time, holders of Company Options have no rights with respect thereto other than those specifically provided in this Section 5.4.

5.5 **Indemnification of Officers and Directors**.

(a) From the Effective Time through the sixth anniversary of the date on which the Effective Time occurs, each of Parent and the Surviving Corporation shall indemnify and hold harmless each Person who is now, or has been at any time prior to the date hereof, or who becomes prior to the Effective Time, a director or officer of Parent or the Company and their respective Subsidiaries, respectively (the "***D&O Indemnified Parties***"), against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys' fees and disbursements and investigation costs (collectively, "***Costs***"), incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to the fact that the D&O Indemnified Party is or was a director or officer of Parent or of the Company, whether asserted or claimed prior to, at or after the Effective Time, in each case, to the fullest extent permitted under applicable Law. Each D&O Indemnified Party will be entitled to advancement of expenses incurred in the defense of any such claim, action, suit, proceeding or investigation from each of Parent and the Surviving Corporation, jointly and severally, upon receipt by Parent or the Surviving Corporation from the D&O Indemnified Party of a request therefor; *provided* that any such Person to whom expenses are advanced provides a written undertaking to Parent, to the extent then required by the DGCL, to repay such advances if it is ultimately determined that such Person is not entitled to indemnification.

(b) The provisions of the certificate of incorporation and bylaws of Parent with respect to indemnification, advancement of expenses and exculpation of present and former directors and officers of Parent that are presently set forth in the certificate of incorporation and bylaws of Parent shall not be amended, modified or repealed for a period of six years from the Effective Time in a manner that would adversely affect the rights thereunder of individuals who, at or prior to the Effective Time, were officers or directors of Parent. The certificate of incorporation and bylaws of the Surviving Corporation shall

contain, and Parent shall cause the certificate of incorporation and bylaws of the Surviving Corporation to so contain, provisions no less favorable with respect to indemnification, advancement of expenses and exculpation of present and former directors and officers as those presently set forth in the certificate of incorporation and bylaws of Parent.

(c) From and after the Effective Time, (i) the Surviving Corporation shall fulfill and honor in all respects the obligations of the Company to its D&O Indemnified Parties as of immediately prior to the Closing pursuant to any indemnification provisions under the Company's Organizational Documents and pursuant to any indemnification agreements between the Company and such D&O Indemnified Parties, with respect to claims arising out of matters occurring at or prior to the Effective Time and (ii) Parent shall fulfill and honor in all respects the obligations of Parent to its D&O Indemnified Parties as of immediately prior to the Closing pursuant to any indemnification provisions under Parent's Organizational Documents and pursuant to any indemnification agreements between Parent and such D&O Indemnified Parties, with respect to claims arising out of matters occurring at or prior to the Effective Time.

(d) From and after the Effective Time, Parent shall maintain directors' and officers' liability insurance policies, with an effective date as of the Closing Date, on commercially available terms and conditions and with coverage limits customary for U.S. public companies similarly situated to Parent. In addition, Parent shall purchase, prior to the Effective Time, a six-year prepaid "tail policy" for the non-cancellable extension of the directors' and officers' liability coverage of Parent's existing directors' and officers' insurance policies for a claims reporting or discovery period of at least six years from and after the Effective Time with respect to any claim related to any period of time at or prior to the Effective Time (the "***D&O Tail Policy***").

(e) From and after the Effective Time, Parent shall pay all expenses, including reasonable attorneys' fees, that are incurred by the persons referred to in this Section 5.5 in connection with their successful enforcement of the rights provided to such persons in this Section 5.5.

(f) The provisions of this Section 5.5 are intended to be in addition to the rights otherwise available to the current and former officers and directors of Parent and the Company by Law, charter, statute, bylaw or agreement, and shall operate for the benefit of, and shall be enforceable by, each of the D&O Indemnified Parties, their heirs and their Representatives. The obligations set forth in this Section 5.9 shall not be terminated, amended or otherwise modified in any manner that adversely affects any D&O Indemnified Party (and their heirs and Representatives) without the prior written consent of such affected D&O Indemnified Party (or their heirs and Representatives).

(g) In the event Parent or the Surviving Corporation or any of their respective successors or assigns (i) consolidates with or merges into any other Person and shall not be the continuing or surviving corporation or entity of such consolidation or merger or (ii) transfers all or substantially all of its properties and assets to any Person, then, and in each such case, proper provision shall be made so that the successors and assigns of Parent or the Surviving Corporation, as the case may be, shall succeed to the obligations set forth in this Section 5.5. Parent shall cause the Surviving Corporation to perform all of the obligations of the Surviving Corporation under this Section 5.5.

5.6 **Additional Agreements**. The Parties shall use commercially reasonable efforts to cause to be taken all actions necessary to consummate the Contemplated Transactions. Without limiting the generality of the foregoing, each Party to this Agreement: (a) shall make all filings and other submissions (if any) and give all notices (if any) required to be made and given by such Party in connection with the Contemplated Transactions; (b) shall use reasonable best efforts to obtain each Consent (if any) reasonably required to be obtained (pursuant to any applicable Law or Contract, or otherwise) by such Party in connection with the Contemplated Transactions or for such Contract (with respect to Contracts set forth in **Schedule 5.6**) to remain in full force and effect; (c) shall use commercially reasonable efforts to lift any injunction prohibiting, or any other legal bar to, the Contemplated Transactions; and (d) shall use commercially reasonable efforts to satisfy the conditions precedent to the consummation of this Agreement.

5.7 **Disclosure**. The initial press release relating to this Agreement shall be a joint press release issued by the Company and Parent and thereafter Parent and the Company shall consult with each other before issuing any further press release(s) or otherwise making any public statement or making any announcement to Parent Associates or Company Associates (to the extent not previously issued or made in accordance with this

Agreement) with respect to the Contemplated Transactions and shall not issue any such press release, public statement or announcement to Parent Associates or Company Associates without the other Party's written consent (which shall not be unreasonably withheld, conditioned or delayed). Notwithstanding the foregoing: (a) each Party may, without such consultation or consent, make any public statement in response to questions from the press, analysts, investors or those attending industry conferences, make internal announcements to employees and make disclosures in Parent SEC Documents, so long as such statements are consistent with previous press releases, public disclosures or public statements made jointly by the parties (or individually, if approved by the other Party); (b) a Party may, without the prior consent of the other Party hereto but subject to giving advance notice to the other Party, issue any such press release or make any such public announcement or statement as may be required by any Law; and (c) Parent need not consult with the Company in connection with such portion of any press release, public statement or filing to be issued or made pursuant to Section 5.3(e) or with respect to any Acquisition Proposal or Parent Board Adverse Recommendation Change.

5.8 **Listing**. Parent shall use its commercially reasonable efforts: (a) to maintain its existing listing on Nasdaq until the Effective Time and to obtain approval of the listing of the combined corporation on Nasdaq; (b) to the extent required by the rules and regulations of Nasdaq, to prepare and submit to Nasdaq a notification form for the listing of the shares of Parent Common Stock to be issued in connection with the Contemplated Transactions, and to cause such shares to be approved for listing (subject to official notice of issuance); (c) to effect the Nasdaq Reverse Split; and (d) to the extent required by Nasdaq Marketplace Rule 5110, to file an initial listing application for the Parent Common Stock on Nasdaq (the "***Nasdaq Listing Application***") and to cause such Nasdaq Listing Application to be conditionally approved prior to the Effective Time. The Parties will use commercially reasonable efforts to coordinate with respect to compliance with Nasdaq rules and regulations. Each Party will promptly inform the other Party of all verbal or written communications between Nasdaq and such Party or its Representatives. Parent and the Company agree to evenly split all Nasdaq fees associated with the Nasdaq Listing Application and the Nasdaq Reverse Split, if any (the "***Nasdaq Fees***"). The Company will cooperate with Parent as reasonably requested by Parent with respect to the Nasdaq Listing Application and promptly furnish to Parent all information concerning the Company and its stockholders that may be required or reasonably requested in connection with any action contemplated by this Section 5.8.

5.9 **Tax Matters**.

(a) For United States federal income Tax purposes, (i) the Parties intend that the Merger qualify as a "reorganization" within the meaning of Section 368(a) of the Code (the "***Intended Tax Treatment***") and (ii) this Agreement is intended to be, and is hereby adopted as, a "plan of reorganization" for purposes of Section 354 and 361 of the Code and Treasury Regulations Section 1.368-2(g) and 1.368-3(a), to which the Parent, Merger Sub and the Company are parties under Section 368(b) of the Code. The Parties shall treat and shall not take any tax reporting position inconsistent with the treatment of the Merger as a reorganization within the meaning of Section 368(a) of the Code for U.S. federal, state and other relevant Tax purposes, unless otherwise required pursuant to a "determination" within the meaning of Section 1313(a) of the Code.

(b) The Parties shall use their respective reasonable best efforts to cause the Merger to qualify, and will not take any action or cause any action to be taken which action would reasonably be expected to prevent the Merger from qualifying, for the Intended Tax Treatment.

(c) Parent shall use its reasonable best efforts to deliver a tax representation letter substantially in the form set forth in Section 5.9(c)(i) of the Parent Disclosure Schedule containing representations of Parent and Merger Sub (the "***Parent Tax Representation Letter***"), dated as of the Closing Date and signed by an officer of Parent to DLA Piper LLP ("***DLA***") Parent and Merger Sub shall use their reasonable best efforts not to, and not permit any Affiliate to, take or cause to be taken any action that would cause to be untrue (or fail to take or cause not to be taken any action which inaction would cause to be untrue) any of the representations and covenants made to DLA in the Parent Tax Representation Letter.

5.10 **Parent Common Stock; Legends**.

(a) The shares of Parent Common Stock issued pursuant to the terms of this Agreement will be issued in a transaction exempt from registration under the Securities Act by reason of Section 4(a)(2) thereof and/or Regulation D promulgated under the Securities Act and may not be re-offered or resold other than in conformity with the registration requirements of the Securities Act and such other applicable rules

and regulations or pursuant to an exemption therefrom. Until the resale by the holders of Company Capital Stock of their shares of Parent Common Stock has become registered under the Securities Act, or otherwise transferable pursuant to an exemption from such registration otherwise required thereunder, the shares of Parent Common Stock issued pursuant to this Agreement shall be characterized as "restricted securities" under the Securities Act and, if certificated, shall bear the following legend (or if held in book entry form, will be noted with a similar restriction):

"THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 (THE "ACT") AND MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, ASSIGNED, PLEDGED OR HYPOTHECATED UNLESS REGISTERED UNDER THE ACT OR UNLESS AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE ACT IS AVAILABLE."

Parent agrees to cooperate in a timely manner with the holders of Registrable Securities to remove any restrictive legends or similar transfer instructions from the Registrable Securities upon the registration of the Registrable Securities or in the event that the Registrable Securities are otherwise transferable pursuant to an exemption from registration otherwise required thereunder.

(b) Parent shall be entitled to place appropriate legends on the book entries and/or certificates evidencing any shares of Parent Common Stock to be received in the Merger by equity holders of the Company who may be considered "affiliates" of Parent for purposes of Rules 144 and 145 under the Securities Act reflecting the restrictions set forth in Rules 144 and 145 and to issue appropriate stop transfer instructions to the transfer agent for Parent Common Stock.

5.11 **Directors and Officers**.

(a) The Parties shall use reasonable best efforts and take all necessary action so that immediately after the Effective Time, (A) the Parent Board is comprised of seven members, with (i) three such members designated by Parent, (ii) three such members designated by the Company and (iii) one remaining member to be mutually agreed upon by the Parties and (B) the Persons listed in **Exhibit D** under the heading "Officers" are elected or appointed, as applicable, to the positions of officers of Parent, as set forth therein, to serve in such positions effective as of the Effective Time until successors are duly appointed and qualified in accordance with applicable Law. If any Person listed in **Exhibit D** is unable or unwilling to serve as an officer of Parent or the Surviving Corporation, as set forth therein, as of the Effective Time, the Parties shall mutually agree upon a successor.

(b) After the Closing, the nominating committee of the Parent Board shall nominate the directors of Parent in the ordinary course.

5.12 **Termination of Certain Agreements and Rights**. The Company shall cause any Investor Agreements (excluding the Company Lock-up Agreements) to be terminated immediately prior to the Effective Time, without any liability being imposed on the part of Parent or the Surviving Corporation.

5.13 **Section 16 Matters**. Prior to the Effective Time, Parent and the Company shall take all such steps as may be required (to the extent permitted under applicable Laws) to cause any acquisitions of Parent Common Stock, restricted stock awards to acquire Parent Common Stock and any options to purchase Parent Common Stock in connection with the Contemplated Transactions, by each individual who is reasonably expected to become subject to the reporting requirements of Section 16(a) of the Exchange Act with respect to Parent, to be exempt under Rule 16b-3 promulgated under the Exchange Act. Promptly following the date of this Agreement and at least 30 days prior to the Closing Date, the Company shall furnish the following information to Parent for each individual who, immediately after the Effective Time, will become subject to the reporting requirements of Section 16(a) of the Exchange Act with respect to Parent: (a) the number of shares of Company Capital Stock owned by such individual and expected to be exchanged for shares of Parent Common Stock pursuant to the Merger, and (b) the number of other derivative securities (if any) with respect to Company Capital Stock owned by such individual and expected to be converted into shares of Parent Common Stock, restricted stock awards to acquire Parent Common Stock or derivative securities with respect to Parent Common Stock in connection with the Merger.

5.14 **Cooperation**. Each Party shall cooperate reasonably with the other Party and shall provide the other Party with such assistance as may be reasonably requested for the purpose of facilitating the performance by each Party of its respective obligations under this Agreement and to enable the combined entity to continue to meet its obligations following the Effective Time.

5.15 **Allocation Certificates**.

(a) The Company will prepare and deliver to Parent at least five Business Days prior to the Closing Date a certificate signed by the Chief Financial Officer of the Company in a form reasonably acceptable to Parent setting forth (as of immediately prior to the Effective Time): (i) each holder of Company Capital Stock and Company Options; (ii) such holder's name and address; (iii) the number and type of Company Capital Stock held and/or underlying the Company Options as of the immediately prior to the Effective Time for each such holder; and (iv) the number of shares of Parent Common Stock to be issued to such holder, or to underlie any Company Option to be issued to such holder, pursuant to this Agreement in respect of the Company Capital Stock or Company Options held by such holder as of immediately prior to the Effective Time (the "***Allocation Certificate***").

(b) Parent will prepare and deliver to the Company at least five Business Days prior to the Closing Date a certificate signed by the Chief Financial Officer of Parent in a form reasonably acceptable to the Company, setting forth as of a reasonably practicable date: (i) each record holder of Parent Common Stock or Parent Options; (ii) such record holder's name and address; and (iii) the number of shares of Parent Common Stock held and/or underlying the Parent Options as of the Effective Time for such holder (the "***Parent Outstanding Shares Certificate***").

5.16 **Company Financial Statements**. As promptly as reasonably practicable following the date of this Agreement and no later than fifteen (15) days following the date of this Agreement the Company will furnish to Parent (i) audited financial statements for the fiscal years ended 2017 and 2018 for inclusion in the Proxy Statement (the "***Company Audited Financial Statements***") and (ii) unaudited interim financial statements for each interim period completed prior to Closing that would be required to be included in the Proxy Statement or any periodic report due prior to the Closing if the Company were subject to the periodic reporting requirements under the Securities Act or the Exchange Act (the "***Company Interim Financial Statements***"). Each of the Company Audited Financial Statements and the Company Interim Financial Statements will be suitable for inclusion in the Proxy Statement and prepared in accordance with GAAP as applied on a consistent basis during the periods involved (except in each case as described in the notes thereto) and on that basis will present fairly, in all material respects, the financial position and the results of operations, changes in stockholders' equity, and cash flows of the Company as of the dates of and for the periods referred to in the Company Audited Financial Statements or the Company Interim Financial Statements, as the case may be.

5.17 **Takeover Statutes**. If any Takeover Statute is or may become applicable to the Contemplated Transactions, each of the Company, the Company Board, Parent and the Parent Board, as applicable, shall grant such approvals and take such actions as are necessary so that the Contemplated Transactions may be consummated as promptly as practicable on the terms contemplated by this Agreement and otherwise act to eliminate or minimize the effects of such statute or regulation on the Contemplated Transactions.

5.18 **Stockholder Litigation**. Parent shall conduct and control the settlement and defense of any stockholder litigation against Parent or any of its directors relating to this Agreement or the Contemplated Transactions. Prior to the Closing, Parent shall reasonably consult with and permit the Company and its Representatives to participate in the defense, negotiations and settlement of any such stockholder litigation, and Parent shall give consideration to the Company's advice with respect to stockholder litigation. Parent shall promptly advise the Company orally and in writing of the initiation of, and shall keep the Company reasonably apprised of any material developments in connection with any such stockholder litigation. The Parties hereto shall reasonably cooperate in resisting any such effort to restrain, enjoin, prohibit or otherwise oppose the Contemplated Transactions.

5.19 **Company Charter Amendment**. The Company shall take all necessary action to file the Amendment to the Company's Amended and Restated Certificate of Incorporation in the form attached hereto as **Exhibit E** (the "**Company Charter Amendment**") with the Secretary of State of the State of Delaware prior to the Effective Time.

5.20 **Private Placement**. Parent intends to issue the shares of Parent Common Stock as provided in this Agreement pursuant to a "private placement" exemption or exemptions from registration under Section 4(a)(2) of the Securities Act and an exemption from qualification under applicable state securities laws. The Company agrees to fully cooperate with Parent in its efforts to ensure that such shares of Parent Common Stock may be issued pursuant to such exemptions and agrees that, in the event any Company Stockholder who is to receive shares of Parent Common Stock hereunder is not an "accredited investor" (within the meaning of Regulation D of the Securities Act), the Company shall arrange for such Company Stockholder to be represented by a "purchaser representative" (within the meaning of Regulation D of the Securities Act).

5.21 **Resale Registration Statement**.

(a) Parent shall prepare and file within ninety (90) days of the Closing Date a registration statement on Form S-3 under the Securities Act, which registration statement shall cover the sale, resale or other distribution of all such shares of Parent Common Stock issued to Company Stockholders pursuant to this Agreement (the "***Registrable Securities***") on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, except that if Parent fails to meet one or more of the registrant requirements specified in General Instruction I.A. on Form S-3, registration shall be on another appropriate form that allows for such Registrable Securities to be registered (the "Resale Registration Statement"), and use commercially reasonable efforts to cause such Resale Registration Statement to become effective by the SEC as promptly as reasonably practicable after the filing thereof (and in any event within 60 days after the filing thereof). Once declared effective, Parent shall, subject to the other applicable provisions of this Agreement, use commercially reasonable efforts to cause the Resale Registration Statement to be continuously effective and usable until the date that is the three-year anniversary of the effective date of such registration, or such earlier time as all shares of Registrable Securities covered by such Registration Statement (i) have been sold pursuant to such Registration Statement or otherwise, (ii) may be transferred under Rule 144 or another similar exemption under the Securities Act without manner of sale or volume restrictions, or (iii) cease to be outstanding (the "***Effectiveness Period***").

(b) Parent shall supplement and amend any Resale Registration Statement if required by the Securities Act. If any Resale Registration Statement ceases to be effective under the Securities Act during the Effectiveness Period, Parent shall use commercially reasonable efforts to as promptly as is reasonably practicable cause such Resale Registration Statement to again become effective under the Securities Act (including obtaining the prompt withdrawal of any order suspending the effectiveness of such Resale Registration Statement), and shall use commercially reasonable efforts to as promptly as is reasonably practicable amend such Resale Registration Statement in a manner reasonably expected to result in the withdrawal of any order suspending the effectiveness of such Resale Registration Statement or file an additional registration statement (a "***Subsequent Shelf Registration***") for an offering to be made on a delayed or continuous basis pursuant to Rule 415 of the Securities Act registering the resale from time to time by the holders thereof of all Registrable Securities issued pursuant to this Agreement as of the time of such filing. If a Subsequent Shelf Registration is filed, Parent shall use commercially reasonable efforts to (i) cause such Subsequent Shelf Registration to become effective under the Securities Act as promptly as is reasonably practicable after the filing thereof and (ii) keep such Subsequent Shelf Registration continuously effective and usable until the end of the Effectiveness Period.

(c) The Company Stockholders receiving Registrable Securities are intended third party beneficiaries of this Section 5.21.

5.22 **Principal Office and Facilities**. After the Closing, (a) the principal office of the Company shall become the principal office of Parent and (b) Parent will maintain substantial operations at its facilities in the Iowa State University Research Park in Ames, Iowa.

Section 6. CONDITIONS PRECEDENT TO OBLIGATIONS OF EACH PARTY

The obligations of each Party to effect the Merger and otherwise consummate the Contemplated Transactions to be consummated at the Closing are subject to the satisfaction or, to the extent permitted by applicable Law, the written waiver by each of the Parties, at or prior to the Closing, of each of the following conditions:

6.1 **No Restraints**. No temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Contemplated Transactions shall have been issued by any court of competent jurisdiction or other Governmental Body of competent jurisdiction and remain in effect and there shall not be any Law which has the effect of making the consummation of the Contemplated Transactions illegal.

6.2 **Stockholder Approval**. (a) Parent shall have obtained the Required Parent Stockholder Vote and (b) the Company shall have obtained the Required Company Stockholder Vote.

6.3 **Listing**. The existing shares of Parent Common Stock shall have been continually listed on Nasdaq as of and from the date of this Agreement through the Closing Date, the approval of the listing of additional shares of Parent Common Stock on Nasdaq shall have been obtained and the shares of Parent Common Stock to be issued in the Merger pursuant to this Agreement shall have been approved for listing (subject to official notice of issuance) on Nasdaq as of the Closing. Parent shall not have received any comment letter from the SEC or the staff thereof or any correspondence from officials of Nasdaq or the staff thereof relating to the delisting or maintenance of listing of the Parent Common Stock on Nasdaq.

Section 7. ADDITIONAL CONDITIONS PRECEDENT TO OBLIGATIONS OF PARENT AND MERGER SUB

The obligations of Parent and Merger Sub to effect the Merger and otherwise consummate the transactions to be consummated at the Closing are subject to the satisfaction or the written waiver by Parent, at or prior to the Closing, of each of the following conditions:

7.1 **Accuracy of Representations**. The Company Fundamental Representations shall have been true and correct in all material respects as of the date of this Agreement and shall be true and correct in all material respects on and as of the Closing Date with the same force and effect as if made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct in all material respects as of such date). The representations and warranties of the Company contained in this Agreement (other than the Company Fundamental Representations) shall have been true and correct as of the date of this Agreement and shall be true and correct on and as of the Closing Date with the same force and effect as if made on the Closing Date, except (a) in each case, or in the aggregate, where the failure to be true and correct would not reasonably be expected to have a Company Material Adverse Effect (without giving effect to any references therein to any Company Material Adverse Effect or other materiality qualifications), or (b) for those representations and warranties which address matters only as of a particular date (which representations shall have been true and correct, subject to the qualifications as set forth in the preceding clause (a), as of such particular date) (it being understood that, for purposes of determining the accuracy of such representations and warranties, any update of or modification to the Company Disclosure Schedule made or purported to have been made after the date of this Agreement shall be disregarded).

7.2 **Performance of Covenants**. The Company shall have performed or complied with in all material respects all agreements and covenants required to be performed or complied with by it under this Agreement at or prior to the Effective Time.

7.3 **Documents**. Parent shall have received the following documents, each of which shall be in full force and effect:

(a) a certificate executed by the Chief Executive Officer or Chief Financial Officer of the Company certifying (i) that the conditions set forth in Sections 7.1, 7.2, 7.5, 7.6 and 7.9 have been duly satisfied and (ii) that the information set forth in the Allocation Certificate delivered by the Company in accordance with Section 5.15 is true and accurate in all respects as of the Closing Date;

(b) the Allocation Certificate; and

(c) a written resignation, in a form reasonably satisfactory to Parent, dated as of the Closing Date and effective as of the Closing, executed by each of the officers and directors of the Company who are otherwise not mutually agreed upon by Parent and the Company to continue as officers or directors of the Company after the Closing.

7.4 **FIRPTA Certificate**. Parent shall have received (i) an original signed statement from the Company that the Company is not, and has not been at any time during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code, a "United States real property holding corporation," as defined in Section 897(c)(2) of the Code, conforming to the requirements of Treasury Regulations Section 1.1445-2(c)(3) and 1.897-2(h) and (ii) an original signed notice to be delivered to the IRS in accordance with the provisions of Treasury Regulations Section 1.897-2(h)(2), together with written authorization for Parent to deliver such notice to the IRS on behalf of the Company following the Closing, each dated as of the Closing Date, duly executed by an authorized officer of the Company, and in form and substance reasonably acceptable to Parent.

7.5 **No Company Material Adverse Effect**. Since the date of this Agreement, there shall not have occurred any Company Material Adverse Effect that is continuing.

7.6 **Termination of Investor Agreements**. The Investor Agreements shall have been terminated.

7.7 **Termination of Specified Agreements**. The agreements listed on Section B of the Company Disclosure Schedule shall have been amended or terminated as specified therein.

7.8 **Company Lock-Up and Support Agreements**. Parent shall have received the Company Lock-Up Agreements and Company Support Agreements duly executed by each of the Company Signatories and each executive officer and director of the Company who is elected or appointed, as applicable, as an executive officer and director of Parent as of immediately following the Closing, each of which shall be in full force and effect.

7.9 **Company Stockholder Written Consent**. The Company Stockholder Written Consent evidencing the Required Company Stockholder Vote shall be in full force and effect.

7.10 **Company Charter Amendment**. The Company shall have filed the Charter Amendment with the Secretary of State of the State of Delaware prior to the Closing, which Charter Amendment shall continue to be in full force and effect as of the Closing.

7.11 **Appraisal Rights**. Either (a) the period during which any holders of any class or series of Company Capital Stock can exercise their statutory appraisal rights under Section 262 of the DGCL with respect to the Merger shall have expired, and the holders of Company Capital Stock representing not more than zero-point-five percent (0.5%) of the votes entitled to be cast by holders of Company Capital Stock entitled to exercise such statutory appraisal rights shall have exercised (and not subsequently withdrawn or waived) such statutory appraisal rights; or (b) the holders of Company Capital Stock representing at least ninety-nine-point-five percent (99.5%) of the votes entitled to be cast by holders of Company Capital Stock entitled to exercise such statutory appraisal rights shall have effectively waived their statutory appraisal rights under Section 262 of the DGCL in connection with the Merger by execution and delivery of a written consent or waiver.

Section 8. ADDITIONAL CONDITIONS PRECEDENT TO OBLIGATION OF THE COMPANY

The obligations of the Company to effect the Merger and otherwise consummate the transactions to be consummated at the Closing are subject to the satisfaction or the written waiver by the Company, at or prior to the Closing, of each of the following conditions:

8.1 **Accuracy of Representations**. The Parent Fundamental Representations shall have been true and correct in all material respects as of the date of this Agreement and shall be true and correct in all material respects on and as of the Closing Date with the same force and effect as if made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct in all material respects as of such date). The representations and warranties of Parent and Merger Sub contained in this Agreement (other than the Parent Fundamental Representations) shall have been true and correct as of the date of this Agreement and shall be true and correct on and as of the Closing Date with the same force and effect as if made on the Closing Date except (a) in each case, or in the aggregate, where the failure to be true and correct would not reasonably be expected

to have a Parent Material Adverse Effect (without giving effect to any references therein to any Parent Material Adverse Effect or other materiality qualifications), or (b) for those representations and warranties which address matters only as of a particular date (which representations shall have been true and correct, subject to the qualifications as set forth in the preceding clause (a), as of such particular date) (it being understood that, for purposes of determining the accuracy of such representations and warranties, any update of or modification to the Parent Disclosure Schedule made or purported to have been made after the date of this Agreement shall be disregarded).

8.2 **Performance of Covenants**. Parent and Merger Sub shall have performed or complied with in all material respects all of their agreements and covenants required to be performed or complied with by each of them under this Agreement at or prior to the Effective Time.

8.3 **Documents**. The Company shall have received the following documents, each of which shall be in full force and effect:

(a) a certificate executed by the Chief Executive Officer or Chief Financial Officer of Parent confirming that the conditions set forth in Sections 8.1, 8.2, and 8.4 have been duly satisfied;

(b) the Parent Outstanding Shares Certificate; and

(c) a written resignation, in a form reasonably satisfactory to the Company, dated as of the Closing Date and effective as of the Closing, executed by each of the officers and directors of Parent who are not to continue as officers or directors of Parent after the Closing pursuant to Section 5.11 hereof.

8.4 **No Parent Material Adverse Effect**. Since the date of this Agreement, there shall not have occurred any Parent Material Adverse Effect.

8.5 **Parent Lock-Up and Support Agreements**. The Company shall have received the Parent Lock-Up Agreements and Parent Support Agreements duly executed by each of the Parent Signatories, each of which shall be in full force and effect.

8.6 **Parent Tax Representation Letter**. DLA shall have received a copy of the Parent Tax Representation Letter.

8.7 **Board of Directors**. Parent shall have caused the Parent Board to be constituted as set forth in Section 5.11 of this Agreement effective as of the Effective Time.

Section 9. TERMINATION

9.1 **Termination**. This Agreement may be terminated prior to the Effective Time (whether before or after adoption of this Agreement by the Company's stockholders and whether before or after approval of the Parent Stockholder Matters by Parent's stockholders, unless otherwise specified below):

(a) by mutual written consent of Parent and the Company;

(b) by either Parent or the Company if the Contemplated Transactions shall not have been consummated by the date that is six months after the date hereof (subject to possible extension as provided in this Section 9.1(b), the "***End Date***"); *provided*, *however*, that the right to terminate this Agreement under this Section 9.1(b) shall not be available to the Company, on the one hand, or to Parent, on the other hand, if such Party's action or failure to act has been a principal cause of the failure of the Contemplated Transactions to occur on or before the End Date and such action or failure to act constitutes a breach of this Agreement that would give the other Party the right to terminate this Agreement pursuant to Section 9.1(g) or Section 9.1(f), as applicable, *provided*, *further*, *however*, that, in the event that a request for additional information has been made by any Governmental Body, or in the event that the SEC has not concluded its review of the preliminary Proxy Statement (whether by confirmation that the SEC has no further comments or expiration of the 10-day waiting period contemplated by Rule 14a-6(a) promulgated under the Exchange Act) by the date which is 60 days prior to the End Date, then either the Company or Parent shall be entitled to extend the End Date for an additional 60 days by written notice to the other the Party;

(c) by either Parent or the Company if a court of competent jurisdiction or other Governmental Body shall have issued a final and nonappealable order, decree or ruling, or shall have taken any other action,

having the effect of permanently restraining, enjoining or otherwise prohibiting the Contemplated Transactions (in each case, to a date following the End Date); *provided*, *however*, that the right to terminate this Agreement under this Section 9.1(c) shall not be available to the Company, on the one hand, or to Parent, on the other hand, if such Party's action or failure to act has been a principal cause of the issuance of such order, decree or ruling or the taking of such other action and such action or failure to act constitutes a breach of this Agreement that would give the other Party the right to terminate this Agreement pursuant to Section 9.1(g) or Section 9.1(f), as applicable;

(d) by Parent if the Company Stockholder Written Consent evidencing the Required Company Stockholder Vote shall not have been obtained immediately following the execution of this Agreement; *provided*, *however*, that if the Company Stockholder Written Consent evidencing the Required Company Stockholder Vote has been obtained and has continuously been in full force and effect, Parent may not terminate this Agreement pursuant to this Section 9.1(d);

(e) by either Parent or the Company if (i) the Parent Stockholders' Meeting (including any adjournments and postponements thereof) shall have been held and completed and Parent's stockholders shall have taken a final vote on the Parent Stockholder Matters and (ii) the Parent Stockholder Matters shall not have been approved at the Parent Stockholders' Meeting (or at any adjournment or postponement thereof) by the Required Parent Stockholder Vote;

(f) by the Company, upon a breach of any representation, warranty, covenant or agreement set forth in this Agreement by Parent or Merger Sub or if any representation or warranty of Parent or Merger Sub shall have become inaccurate, in either case, such that the conditions set forth in Section 8.1 or Section 8.2 would not be satisfied as of the time of such breach or as of the time such representation or warranty shall have become inaccurate; *provided* that the Company is not then in material breach of any representation, warranty, covenant or agreement under this Agreement; *provided*, *further*, that if such inaccuracy in Parent's or Merger Sub's representations and warranties or breach by Parent or Merger Sub is curable by the End Date by Parent or Merger Sub, then this Agreement shall not terminate pursuant to this Section 9.1(f) as a result of such particular breach or inaccuracy until the expiration of a 30-day period commencing upon delivery of written notice from the Company to Parent or Merger Sub of such breach or inaccuracy and its intention to terminate pursuant to this Section 9.1(f) (it being understood that this Agreement shall not terminate pursuant to this Section 9.1(f) as a result of such particular breach or inaccuracy if such breach by Parent or Merger Sub is cured prior to such termination becoming effective);

(g) by Parent, upon a breach of any representation, warranty, covenant or agreement set forth in this Agreement by the Company or if any representation or warranty of the Company shall have become inaccurate, in either case, such that the conditions set forth in Section 7.1 or Section 7.2 would not be satisfied as of the time of such breach or as of the time such representation or warranty shall have become inaccurate; *provided* that Parent is not then in material breach of any representation, warranty, covenant or agreement under this Agreement; *provided*, *further*, that if such inaccuracy in the Company's representations and warranties or breach by the Company is curable by the End Date by the Company then this Agreement shall not terminate pursuant to this Section 9.1(g) as a result of such particular breach or inaccuracy until the expiration of a 30-day period commencing upon delivery of written notice from Parent to the Company of such breach or inaccuracy and its intention to terminate pursuant to this Section 9.1(g) (it being understood that this Agreement shall not terminate pursuant to this Section 9.1(g) as a result of such particular breach or inaccuracy if such breach by the Company is cured prior to such termination becoming effective); or

(h) by the Company, if the Parent Board shall have effected a Parent Board Adverse Recommendation Change.

9.2 **Effect of Termination**. In the event of the termination of this Agreement as provided in Section 9.1, this Agreement shall be of no further force or effect; *provided*, *however*, that (a) this Section 9.2, Section 5.7, Section 9.3, Section 10 and the definitions of the defined terms in such Sections shall survive the termination of this Agreement and shall remain in full force and effect and (b) the termination of this Agreement and the provisions of Section 9.3 shall not relieve any Party of any liability for fraud or for any willful and material breach of any representation, warranty, covenant, obligation or other provision contained in this Agreement.

9.3 **Expenses; Termination Fees**.

(a) Whether or not the Merger is consummated, (i) all Parent Transaction Expenses shall be paid by Parent (or on behalf of Parent) at or prior to the Closing and (ii) all Company Transaction Expenses shall be paid by the Company.

(b) If this Agreement is terminated (i) by Parent pursuant to Section 9.1(d), or (ii) by the Company pursuant to Section 9.1(b) and the Company Stockholder Written Consent evidencing the Required Company Stockholder Vote has not been obtained by the Company, then the Company shall pay to Parent within five Business Days of such termination an amount equal to $2,000,000.

(c) If (i) this Agreement is terminated by either Parent or the Company pursuant to Section 9.1(e), or (ii) by Parent pursuant to Section 9.1(b) and the Required Parent Stockholder Vote has not been obtained by Parent, then Parent shall pay to the Company within five Business Days of such termination an amount equal to $2,000,000.

(d) If this Agreement is terminated by the Company pursuant to Section 9.1(h), then Parent shall pay to the Company within five Business Days of such termination an amount equal to $2,000,000.

(e) Any fee payable by the Company or Parent under Section 9.2 or this Section 9.3 shall be paid by wire transfer of same day funds. If a Party fails to pay when due any amount payable by it under Section 9.2 or this Section 9.3, then such Party shall pay to the other Party interest on such overdue amount (for the period commencing as of the date such overdue amount was originally required to be paid and ending on the date such overdue amount is actually paid to the other Party in full) at a rate per annum equal to the "prime rate" (as published in *The Wall Street Journal* or any successor thereto) in effect on the date such overdue amount was originally required to be paid.

(f) The Parties agree that, (i) subject to Section 9.2, any fee payable by Parent to the Company under this Section 9.3, in the circumstances in which it is owed in accordance with the terms of this Agreement, constitute the sole and exclusive remedy of the Company following the termination of this Agreement under the circumstances described in this Section 9.3, it being understood that in no event shall Parent be required to pay the amounts payable pursuant to this Section 9.3 on more than one occasion and (ii) following payment of any fee payable by Parent to the Company under this Section 9.3 (A) Parent shall have no further liability to the Company in connection with or arising out of this Agreement or the termination thereof, any breach of this Agreement by Parent giving rise to such termination, or the failure of the Contemplated Transactions to be consummated, (B) neither the Company nor any of its Affiliates shall be entitled to bring or maintain any other claim, action or proceeding against Parent or Merger Sub or seek to obtain any recovery, judgment or damages of any kind against such Parties (or any partner, member, stockholder, director, officer, employee, Subsidiary, Affiliate, agent or other Representative of such Parties) in connection with or arising out of this Agreement or the termination thereof, any breach by any such Parties giving rise to such termination or the failure of the Contemplated Transactions to be consummated and (C) the Company and its Affiliates shall be precluded from any other remedy against Parent, Merger Sub and their respective Affiliates, at law or in equity or otherwise, in connection with or arising out of this Agreement or the termination thereof, any breach by such Party giving rise to such termination or the failure of the Contemplated Transactions to be consummated; *provided*, *however*, that nothing in this Section 9.3(f) shall limit the rights of Parent and Merger Sub under Section 10.11.

(g) The Parties agree that, (i) subject to Section 9.2, any fee payable by the Company to Parent under this Section 9.3 shall, in the circumstances in which it is owed in accordance with the terms of this Agreement, constitute the sole and exclusive remedy of Parent following the termination of this Agreement under the circumstances described in this Section 9.3, it being understood that in no event shall the Company be required to pay the amounts payable pursuant to this Section 9.3 on more than one occasion and (ii) following payment of any fee payable by the Company to Parent under this Section 9.3 (A) the Company shall have no further liability to Parent in connection with or arising out of this Agreement or the termination thereof, any breach of this Agreement by the Company giving rise to such termination, or the failure of the Contemplated Transactions to be consummated, (B) neither Parent nor any of its Affiliates shall be entitled to bring or maintain any other claim, action or proceeding against the Company or seek to obtain any recovery, judgment or damages of any kind against such Parties (or any partner, member, stockholder, director, officer, employee, Subsidiary, Affiliate, agent or other Representative of such Parties)

in connection with or arising out of this Agreement or the termination thereof, any breach by any such Parties giving rise to such termination or the failure of the Contemplated Transactions to be consummated and (C) Parent and its Affiliates shall be precluded from any other remedy against the Company and its Affiliates, at law or in equity or otherwise, in connection with or arising out of this Agreement or the termination thereof, any breach by such Party giving rise to such termination or the failure of the Contemplated Transactions to be consummated; *provided*, *however*, that nothing in this Section 9.3(g) shall limit the rights of the Company under Section 10.11.

(h) Each of the Parties acknowledges that (i) the agreements contained in this Section 9.3 are an integral part of the Contemplated Transactions, (ii) without these agreements, the Parties would not enter into this Agreement and (iii) any amount payable pursuant to this Section 9.3 is not a penalty, but rather is liquidated damages in a reasonable amount that will compensate the Company in the circumstances in which such amount is payable.

Section 10. MISCELLANEOUS PROVISIONS

10.1 **Non-Survival of Representations and Warranties**. The representations and warranties of the Company, Parent and Merger Sub contained in this Agreement or any certificate or instrument delivered pursuant to this Agreement shall terminate at the Effective Time, and only the covenants that by their terms survive the Effective Time and this Section 10 shall survive the Effective Time.

10.2 **Amendment**. This Agreement may be amended with the approval of the respective boards of directors of the Company, Merger Sub and Parent at any time (whether before or after the adoption and approval of this Agreement by the Company's stockholders or before or after obtaining the Required Parent Stockholder Vote); *provided*, *however*, that after any such approval of this Agreement by a Party's stockholders, no amendment shall be made which by Law requires further approval of such stockholders without the further approval of such stockholders. This Agreement may not be amended except by an instrument in writing signed on behalf of each of the Company, Merger Sub and Parent.

10.3 **Waiver**.

(a) No failure on the part of any Party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any Party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

(b) No Party shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Party and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

10.4 **Entire Agreement; Counterparts; Exchanges by Electronic Transmission**. This Agreement and the other agreements referred to in this Agreement constitute the entire agreement and supersede all prior agreements and understandings, both written and oral, among or between any of the Parties with respect to the subject matter hereof and thereof; *provided*, *however*, that the Confidentiality Agreement shall not be superseded and shall remain in full force and effect in accordance with its terms. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by all Parties by electronic transmission in .PDF format shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

10.5 **Applicable Law; Jurisdiction; Waiver of Jury Trial**.

(a) This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of laws. In any action or proceeding between any of the Parties arising out of or relating to this Agreement or any of the Contemplated Transactions, each of the Parties: (a) irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the Court of Chancery of the State of Delaware or,

to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware or, to the extent that neither of the foregoing courts has jurisdiction, the Superior Court of the State of Delaware; (b) agrees that all claims in respect of such action or proceeding shall be heard and determined exclusively in accordance with clause (a) of this Section 10.5; (c) waives any objection to laying venue in any such action or proceeding in such courts; (d) waives any objection that such courts are an inconvenient forum or do not have jurisdiction over any Party; and (e) agrees that service of process upon such Party in any such action or proceeding shall be effective if notice is given in accordance with Section 10.8 of this Agreement.

(b) EACH PARTY TO THIS AGREEMENT HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT TO TRIAL BY JURY OF ANY CLAIM, DEMAND, ACTION, OR CAUSE OF ACTION (i) ARISING UNDER THIS AGREEMENT OR (ii) IN ANY WAY CONNECTED WITH OR RELATED OR INCIDENTAL TO THE DEALINGS OF THE PARTIES HERETO IN RESPECT OF THIS AGREEMENT OR ANY OF THE CONTEMPLATED TRANSACTIONS, IN EACH CASE WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER IN CONTRACT, TORT, EQUITY, OR OTHERWISE. EACH PARTY TO THIS AGREEMENT HEREBY AGREES AND CONSENTS THAT ANY SUCH CLAIM, DEMAND, ACTION, OR CAUSE OF ACTION SHALL BE DECIDED BY COURT TRIAL WITHOUT A JURY AND THAT THE PARTIES TO THIS AGREEMENT MAY FILE AN ORIGINAL COUNTERPART OF A COPY OF THIS AGREEMENT WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENT OF THE PARTIES HERETO TO THE WAIVER OF THEIR RIGHT TO TRIAL BY JURY.

10.6 **Attorneys' Fees**. In any action at law or suit in equity to enforce this Agreement or the rights of any of the Parties, the prevailing Party in such action or suit (as determined by a court of competent jurisdiction) shall be entitled to recover its reasonable out-of-pocket attorneys' fees and all other reasonable costs and expenses incurred in such action or suit.

10.7 **Assignability**. This Agreement shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the Parties and their respective successors and permitted assigns; *provided*, *however*, that neither this Agreement nor any of a Party's rights or obligations hereunder may be assigned or delegated by such Party without the prior written consent of the other Party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by such Party without the other Party's prior written consent shall be void and of no effect.

10.8 **Notices**. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly delivered and received hereunder (a) one Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable international overnight courier service, (b) upon delivery in the case of delivery by hand, or (c) on the date delivered in the place of delivery if sent by email (with a written or electronic confirmation of delivery) prior to 5:00 p.m. Central time, otherwise on the next succeeding Business Day, in each case to the intended recipient as set forth below:

if to Parent or Merger Sub:

NewLink Genetics Corporation
2503 South Loop Drive
Ames, IA 50010
Attention: Carl Langren, Brad Powers
Email: clangren@linkp.com, bpowers@linkp.com

with a copy to (which shall not constitute notice):

Cooley LLP
380 Interlocken Crescent, Suite 900
Broomfield, CO 80021
Attention: James C.T. Linfield, Laura Medina
Email: linfieldjct@cooley.com, lmedina@cooley.com

if to the Company:

Lumos Pharma, Inc.
4200 Marathon Blvd., Suite 200
Austin, Texas 78756
Attention: Rick Hawkins, President & Chief Executive Officer
Email: rhawkins@lumos-pharma.com

with a copy to (which shall not constitute notice):

DLA Piper LLP (US)
401 Congress, Suite 2500
Austin, Texas 78701
Attention: Samer M. Zabaneh, P.C.
Email: Samer.Zabaneh@dlapiper.com

10.9 **Cooperation**. Each Party agrees to cooperate fully with the other Party and to execute and deliver such further documents, certificates, agreements and instruments and to take such other actions as may be reasonably requested by the other Party to evidence or reflect the Contemplated Transactions and to carry out the intent and purposes of this Agreement.

10.10 **Severability**. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions of this Agreement or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any term or provision of this Agreement is invalid or unenforceable, the Parties agree that the court making such determination shall have the power to limit such term or provision, to delete specific words or phrases or to replace such term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be valid and enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the Parties agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term or provision.

10.11 **Other Remedies; Specific Performance**. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy will not preclude the exercise of any other remedy. The Parties agree that irreparable damage for which monetary damages, even if available, would not be an adequate remedy, would occur in the event that any Party does not perform the provisions of this Agreement (including failing to take such actions as are required of it hereunder to consummate this Agreement) in accordance with its specified terms or otherwise breaches such provisions. Accordingly, the Parties acknowledge and agree that the Parties shall be entitled to an injunction, specific performance and other equitable relief to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof, in addition to any other remedy to which they are entitled at law or in equity. Each of the Parties agrees that it will not oppose the granting of an injunction, specific performance or other equitable relief on the basis that any other Party has an adequate remedy at law or that any award of specific performance is not an appropriate remedy for any reason at law or in equity. Any Party seeking an injunction or injunctions to prevent breaches of this Agreement shall not be required to provide any bond or other security in connection with any such order or injunction.

10.12 **No Third Party Beneficiaries**. Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person (other than the Parties, the D&O Indemnified Parties and the Company Stockholders receiving Registrable Securities to the extent of their respective rights pursuant to Section 5.5 and Section 5.21) any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

10.13 **Construction**.

(a) References to "cash," "dollars" or "$" are to U.S. dollars.

(b) For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; the masculine gender shall include the feminine and neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include masculine and feminine genders.

(c) The Parties have participated jointly in the negotiating and drafting of this Agreement and agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provision of this Agreement.

(d) As used in this Agreement, the words "include" and "including," and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words "without limitation."

(e) Except as otherwise indicated, all references in this Agreement to "Sections," "Exhibits" and "Schedules" are intended to refer to Sections of this Agreement and Exhibits and Schedules to this Agreement, respectively.

(f) Any reference to legislation or to any provision of any legislation shall include any modification, amendment, re-enactment thereof, any legislative provision substituted therefore and all rules, regulations, and statutory instruments issued or related to such legislations.

(g) The bold-faced headings and table of contents contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

(h) The Parties agree that each of the Company Disclosure Schedule and the Parent Disclosure Schedule shall be arranged in sections and subsections corresponding to the numbered and lettered sections and subsections contained in this Agreement. The disclosures in any section or subsection of the Company Disclosure Schedule or the Parent Disclosure Schedule shall qualify other sections and subsections in this Agreement to the extent it is reasonably apparent on its face from a reading of the disclosure that such disclosure is applicable to such other sections and subsections.

(i) Each of "delivered" or "made available" means, with respect to any documentation, that prior to 11:59 p.m. (Central time) on the date that is two Business Days prior to the date of this Agreement (i) a copy of such material has been posted to and made available by a Party to the other Party and its Representatives in the electronic data room maintained by such disclosing Party or (ii) such material is disclosed in the Parent SEC Documents filed with the SEC prior to the date hereof and publicly made available on the SEC's Electronic Data Gathering Analysis and Retrieval system.

(j) Whenever the last day for the exercise of any privilege or the discharge of any duty hereunder shall fall upon a Saturday, Sunday, or any date on which banks in New York, New York are authorized or obligated by Law to be closed, the Party having such privilege or duty may exercise such privilege or discharge such duty on the next succeeding day which is a regular Business Day.

(Remainder of page intentionally left blank)

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date first above written.

NEWLINK GENETICS CORPORATION

By: /s/ Brad Powers
Name: Brad Powers
Title: Office of the Chief Executive Officer

CYCLONE MERGER SUB, INC.

By: /s/ Brad Powers
Name: Brad Powers
Title: President

LUMOS PHARMA, INC.

By: /s/ Richard J. Hawkins
Name: Richard J. Hawkins
Title: President and Chief Executive Officer

SIGNATURE PAGE TO MERGER AGREEMENT

EXHIBIT A

CERTAIN DEFINITIONS

(a) For purposes of this Agreement (including this Exhibit A):

"***Acquisition Inquiry***" means, with respect to a Party, an inquiry, indication of interest or request for information (other than an inquiry, indication of interest or request for information made or submitted by the Company, on the one hand, or Parent, on the other hand, to the other Party) that could reasonably be expected to lead to an Acquisition Proposal.

"***Acquisition Proposal***" means, with respect to a Party, any offer or proposal, whether written or oral (other than an offer or proposal made or submitted by or on behalf of the Company or any of its Affiliates, on the one hand, or by or on behalf of Parent or any of its Affiliates, on the other hand, to the other Party) contemplating or otherwise relating to any Acquisition Transaction with such Party.

"***Acquisition Transaction***" means any transaction or series of related transactions involving:

(i) any merger, consolidation, amalgamation, share exchange, business combination, issuance of securities, acquisition of securities, reorganization, recapitalization, tender offer, exchange offer or other similar transaction: (i) in which a Party is a constituent Entity; (ii) in which a Person or "group" (as defined in the Exchange Act and the rules promulgated thereunder) of Persons directly or indirectly acquires beneficial or record ownership of securities representing more than 20% of the outstanding securities of any class of voting securities of a Party or any of its Subsidiaries; or (iii) in which a Party or any of its Subsidiaries issues securities representing more than 20% of the outstanding securities of any class of voting securities of such Party or any of its Subsidiaries; or

(ii) any sale, lease, exchange, transfer, license, acquisition or disposition of any business or businesses or assets that constitute or account for 20% or more of the consolidated book value or the fair market value of the assets of a Party and its Subsidiaries, taken as a whole.

"***Affiliate***" of a Person means any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. The term "control" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by Contract or otherwise.

"***Agreement***" means the Agreement and Plan of Merger and Reorganization to which this **Exhibit A** is attached, as it may be amended from time to time.

"***Business Day***" means any day other than a Saturday, Sunday or other day on which banks in New York, New York are authorized or obligated by Law to be closed.

"***Code***" means the Internal Revenue Code of 1986, as amended.

"***Company Associate***" means any current or former employee, independent contractor, officer or director of the Company.

"***Company Board***" means the board of directors of the Company.

"***Company Capital Stock***" means the Company Common Stock and the Company Preferred Stock.

"***Company Common Stock***" means the Common Stock, $0.0001 par value per share, of the Company.

"***Company Contract***" means any Contract: (a) to which the Company is a Party; (b) by which the Company or any Company IP or any other asset of the Company is or may become bound or under which the Company has, or may become subject to, any obligation; or (c) under which the Company Subsidiaries has or may acquire any right or interest.

"***Company ERISA Affiliate***" means any corporation or trade or business (whether or not incorporated) which is (or at any relevant time in the past six (6) years was) treated with the Company as a single employer within the meaning of Section 414 of the Code.

"***Company Fundamental Representations***" means the representations and warranties of the Company set forth in Sections 2.1 (Due Organization; Subsidiaries), 2.3 (Authority; Binding Nature of Agreement), 2.6(a) and (c) (Capitalization) and 2.20 (No Financial Advisors).

"***Company IP***" means all Intellectual Property Rights that are owned or purported to be owned by, assigned to, or exclusively licensed by, the Company or its Subsidiaries.

"***Company Material Adverse Effect***" means any Effect that, considered together with all other Effects that have occurred prior to the date of determination of the occurrence of a Company Material Adverse Effect, has or would reasonably be expected to have a material adverse effect on the business, financial condition, assets, liabilities or results of operations of the Company; *provided*, *however*, that Effects arising or resulting from the following shall not be taken into account in determining whether there has been a Company Material Adverse Effect: (a) general business, economic or political conditions affecting the industry in which the Company operates, (b) any natural disaster or any acts of war, armed hostilities or terrorism, (c) changes in financial, banking or securities markets, (d) the failure of the Company to meet internal or analysts' expectations or projections or the results of operations of the Company, (e) any clinical trial programs or studies, including any adverse data, event or outcome arising out of or relating to any such programs or studies, (f) any change in, or any compliance with or action taken for the purpose of complying with, any Law or GAAP (or interpretations of any Law or GAAP), (g) resulting from the announcement of this Agreement or the pendency of the Contemplated Transactions, or (h) resulting from the taking of any action, or the failure to take any action, by the Company that is required to be taken by this Agreement; except in each case with respect to clauses (a) through (c), to the extent disproportionately affecting the Company relative to other similarly situated companies in the industries in which the Company operates.

"***Company Merger Shares***" means a number equal to the total number of shares of Parent Common Stock outstanding immediately prior to the Effective Time, excluding (i) the issuance of shares of Parent Common Stock in respect of all Parent Options and other outstanding options, warrants or rights to receive such shares, in each case, outstanding as of immediately prior to the Effective Time; and (ii) any shares of Parent Common Stock reserved for issuance.

"***Company Options***" means options or other rights to purchase shares of Company Common Stock issued by the Company.

"***Company Plans***" means the Company 2012 Equity Incentive Plan and Company 2016 Stock Plan, as amended.

"***Company Stockholder Matters***" means the following matters relating to the stockholders of the Company: (i) adopting and approving this Agreement and the Contemplated Transactions (including the adoption and filing of the Company Charter Amendment), (ii) acknowledging that the approval given thereby is irrevocable and that such stockholder is aware of its rights to demand appraisal for its shares pursuant to Section 262 of the DGCL, a true and correct copy of which will be attached thereto, and that such stockholder has received and read a copy of Section 262 of the DGCL, and (iii) acknowledging that by its approval of the Merger it is not entitled to appraisal rights with respect to its shares in connection with the Merger and thereby waives any rights to receive payment of the fair value of its capital stock under the DGCL.

"***Company Transaction Expenses***" means all fees and expenses incurred by the Company at or prior to the Effective Time in connection with the Contemplated Transactions and this Agreement, including any fees and expenses of legal counsel and accountants, the maximum amount of fees and expenses payable to financial advisors, investment bankers, brokers, consultants, and other advisors of the Company.

"***Company Unaudited Interim Balance Sheet***" means the unaudited balance sheet of the Company for the period ended June 30, 2019 provided to Parent prior to the date of this Agreement.

"***Confidentiality Agreement***" means the Mutual Confidential Disclosure Agreement, dated as of July 19, 2019, between the Company and Parent.

"***Consent***" means any approval, consent, ratification, permission, waiver or authorization (including any Governmental Authorization).

"***Consideration***" means the number of shares of Parent Common Stock to be issued to the holders of Company Capital Stock as contemplated by Section 1.5 of this Agreement and the number of Parent Options to be substituted for the Company Options to be assumed by Parent as contemplated by Section 5.4.

"***Contemplated Transactions***" means the Merger, the adoption and filing of the Company Charter Amendment and the other transactions and actions contemplated by this Agreement, including the Nasdaq Reverse Split.

"***Contract***" means, with respect to any Person, any written or oral agreement, contract, subcontract, lease (whether for real or personal property), mortgage, license, sublicense or other legally binding commitment or undertaking of any nature to which such Person is a party or by which such Person or any of its assets are bound or affected under applicable Law.

"***DGCL***" means the General Corporation Law of the State of Delaware.

"***Effect***" means any effect, change, event, circumstance, or development.

"***Encumbrance***" means any lien, pledge, hypothecation, charge, mortgage, security interest, lease, license, option, easement, reservation, servitude, adverse title, claim, infringement, interference, option, right of first refusal, preemptive right, community property interest or restriction or encumbrance of any nature (including any restriction on the voting of any security, any restriction on the transfer of any security or other asset, any restriction on the receipt of any income derived from any asset, any restriction on the use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset).

"***Enforceability Exceptions***" means the (a) Laws of general application relating to bankruptcy, insolvency and the relief of debtors; and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

"***Entity***" means any corporation (including any non-profit corporation), partnership (including any general partnership, limited partnership or limited liability partnership), joint venture, estate, trust, company (including any company limited by shares, limited liability company or joint stock company), firm, society or other enterprise, association, organization or entity, and each of its successors.

"***Environmental Law***" means any federal, state, local or foreign Law relating to pollution or protection of human health or the environment (including ambient air, surface water, ground water, land surface or subsurface strata), including any Law or regulation relating to emissions, discharges, releases or threatened releases of Hazardous Materials, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials.

"***ERISA***" means the Employee Retirement Income Security Act of 1974, as amended.

"***Exchange Act***" means the Securities Exchange Act of 1934.

"***Exchange Ratio***" means (i) with respect to Company Common Stock, the Per Share Common Stock Exchange Ratio, (ii) with respect to the Company's Series A Preferred Stock, the Per Share Series A Exchange Ratio, and (iii) with respect to the Company's Series B Preferred Stock, the Per Share Series B Exchange Ratio, each as defined in the Company Charter Amendment.

"***GAAP***" means generally accepted accounting principles and practices in effect from time to time within the United States applied consistently throughout the period involved.

"***Governmental Authorization***" means any: (a) permit, license, certificate, certification, franchise, permission, approval, exemption, variance, exception, order, clearance, registration, qualification or authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Body or pursuant to any Law; or (b) right under any Contract with any Governmental Body.

"***Governmental Body***" means any: (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, department, agency, commission, bureau, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or Entity and any court or other tribunal, and for the avoidance of doubt, any taxing authority); or (d) self-regulatory organization (including Nasdaq).

"***Hazardous Materials***" means any pollutant, chemical, substance and any toxic, infectious, carcinogenic, reactive, corrosive, ignitable or flammable chemical, or chemical compound, or hazardous substance, material or waste, whether solid, liquid or gas, that is subject to regulation, control or remediation under any Environmental Law, including without limitation, crude oil or any fraction thereof, and petroleum products or by-products.

"***Intellectual Property Rights***" means and includes all intellectual property or other proprietary rights under the laws of any jurisdiction in the world, including, without limitation: (a) rights associated with works of authorship, including exclusive exploitation rights, copyrights, moral rights, software, databases, and mask works; (b) trademarks, service marks, trade dress, logos, trade names and other source identifiers, domain names and URLs and similar rights and any and all goodwill associated therewith; (c) rights associated with trade secrets, know how, inventions, invention disclosures, methods, processes, protocols, specifications, techniques and other forms of technology; (d) patents and industrial property rights; and (e) other similar proprietary rights in intellectual property of every kind and nature; (f) rights of privacy and publicity; and (g) all registrations, renewals, extensions, statutory invention registrations, provisionals, continuations, continuations-in-part, provisionals, divisions, or reissues of, and applications for, any of the rights referred to in clauses "(a)" through "(f)" above (whether or not in tangible form and including all tangible embodiments of any of the foregoing, such as samples, studies and summaries), along with all rights to prosecute and perfect the same through administrative prosecution, registration, recordation or other administrative proceeding, and all causes of action and rights to sue or seek other remedies arising from or relating to the foregoing, including for past, present or future infringement of any of the foregoing.

"***IRS***" means the United States Internal Revenue Service.

"***Knowledge***" means, with respect to an individual, that such individual is actually aware of the relevant fact. Any Person that is an Entity shall have Knowledge if any officer or director of such Person as of the date such knowledge is imputed has Knowledge of such fact or other matter.

"***Law***" means any federal, state, national, foreign, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body (including under the authority of Nasdaq or the Financial Industry Regulatory Authority).

"***Legal Proceeding***" means any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Body or any arbitrator or arbitration panel.

"***Merger Sub Board***" means the board of directors of Merger Sub.

"***Nasdaq***" means the Nasdaq Stock Market, including the Nasdaq Global Market or such other Nasdaq market on which shares of Parent Common Stock are then listed.

"***Nasdaq Reverse Split***" means a reverse stock split of all outstanding shares of Parent Common Stock at a reverse stock split ratio as mutually agreed to by Parent and the Company that is effected by Parent for the purpose of maintaining compliance with Nasdaq listing standards.

"***Ordinary Course of Business***" means, in the case of each of the Company and Parent, such actions taken in the ordinary course of its normal operations and consistent with its past practices.

"***Organizational Documents***" means, with respect to any Person (other than an individual), (a) the certificate or articles of association or incorporation or organization or limited partnership or limited liability company, and any joint venture, limited liability company, operating or partnership agreement and other similar documents adopted or filed in connection with the creation, formation or organization of such Person and (b) all bylaws, regulations and similar documents or agreements relating to the organization or governance of such Person, in each case, as amended or supplemented.

"***Parent Associate***" means any current or former employee, independent contractor, officer or director of Parent.

"***Parent Balance Sheet***" means the unaudited balance sheet of Parent as of June 30, 2019 (the "***Parent Balance Sheet Date***"), included in Parent's Report on Form 10-Q for the quarterly period ended June 30, 2019, as filed with the SEC.

"***Parent Board***" means the board of directors of Parent.

"***Parent Change in Circumstance***" means a change in circumstances (other than an Acquisition Proposal) that affects the business, assets or operations of Parent that occurs or arises after the date of this Agreement.

"***Parent Closing Price***" means the volume weighted average closing trading price of a share of Parent Common Stock on Nasdaq for the five consecutive trading days ending five trading days immediately prior to the date of this Agreement.

"***Parent Common Stock***" means the Common Stock, $0.01 par value per share, of Parent.

"***Parent Contract***" means any Contract: (a) to which Parent or Merger Sub is a party; (b) by which Parent, Merger Sub or any Parent IP or any other asset of Parent or Merger Sub is or may become bound or under which Parent or Merger Sub has, or may become subject to, any obligation; or (c) under which Parent or Merger Sub has or may acquire any right or interest.

"***Parent ERISA Affiliate***" means any corporation or trade or business (whether or not incorporated) which is (or at any relevant time was) treated with Parent or any of its Subsidiaries as a single employer within the meaning of Section 414 of the Code.

"***Parent Fundamental Representations***" means the representations and warranties of Parent and Merger Sub set forth in Sections 3.1(a) and (b) (Due Organization; Subsidiaries), 3.3 (Authority; Binding Nature of Agreement), 3.6(a) and (c) (Capitalization) and 3.20 (No Financial Advisors).

"***Parent IP***" means all Intellectual Property Rights that are owned or purported to be owned by, assigned to, or exclusively licensed by, Parent or its Subsidiaries.

"***Parent Material Adverse Effect***" means any Effect that, considered together with all other Effects that have occurred prior to the date of determination of the occurrence of a Parent Material Adverse Effect, has or would reasonably be expected to have a material adverse effect on the business, financial condition, assets, liabilities or results of operations of Parent; *provided*, *however*, that Effects arising or resulting from the following shall not be taken into account in determining whether there has been a Parent Material Adverse Effect: (a) general business, economic or political conditions affecting the industry in which Parent operates, (b) any natural disaster or any acts of war, armed hostilities or terrorism, (c) changes in financial, banking or securities markets, (d) the taking of any action required to be taken by this Agreement, (e) any change in the stock price or trading volume of Parent Common Stock (it being understood, however, that any Effect causing or contributing to any change in stock price or trading volume of Parent Common Stock may be taken into account in determining whether a Parent Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition), (f) the failure of Parent to meet internal or analysts' expectations or projections or the results of operations of Parent; (g) any clinical trial programs or studies, including any adverse data, event or outcome arising out of or related to any such programs or studies; (h) any change in, or any compliance with or action taken for the purpose of complying with, any Law or GAAP (or interpretations of any Law or GAAP); (i) resulting from the announcement of this Agreement or the pendency of the Contemplated Transactions; or (j) resulting from the taking of any action or the failure to take any action, by Parent that is required to be taken by this Agreement, except in each case with respect to clauses (a) through (c), to the extent disproportionately affecting Parent relative to other similarly situated companies in the industries in which Parent operates.

"***Parent Options***" means options or other rights to purchase shares of Parent Common Stock issued by Parent.

"***Parent Stock Plans***" means, the Parent 2000 Equity Incentive Plan, the Parent 2009 Equity Incentive Plan, and the Parent 2010 Non-Employee Directors' Stock Award Plan, in each case, as may be amended from time to time.

"***Parent Transaction Expenses***" means all fees and expenses incurred by Parent at or prior to the Effective Time in connection with the Contemplated Transactions and this Agreement, including (a) any fees and expenses of legal counsel and accountants, the maximum amount of fees and expenses payable to financial advisors, investment bankers, brokers, consultants, and other advisors of Parent; (b) 100% of (i) the fees paid to the SEC in connection with filing the Proxy Statement, and any amendments and supplements thereto with the SEC; (ii) the Nasdaq Fees; (iii) the fees and expenses paid or payable to the Exchange Agent pursuant to the engagement agreement with the Exchange Agent; (iv) any fees and expenses incurred by Parent's financial printer or proxy solicitor in connection with the filing and distribution of the Proxy Statement and any amendments and supplements thereto with the SEC (without duplication of the fees and expenses addressed in clause (b)(i) above); and (v) 100% of the D&O Tail Policy.

"***Party***" or "***Parties***" means the Company, Merger Sub and Parent.

"***Permitted Encumbrance***" means: (a) any liens for current Taxes not yet due and payable or for Taxes that are being contested in good faith and, in each case, for which adequate reserves have been made on the Company

Unaudited Interim Balance Sheet or the Parent Balance Sheet, as applicable, in accordance with GAAP; (b) minor liens that have arisen in the Ordinary Course of Business and that do not (in any case or in the aggregate) materially detract from the value of the assets or properties subject thereto or materially impair the operations of the Company or any of its Subsidiaries or Parent, as applicable; (c) statutory liens to secure obligations to landlords, lessors or renters under leases or rental agreements; (d) deposits or pledges made in connection with, or to secure payment of, workers' compensation, unemployment insurance or similar programs mandated by Law; (e) non-exclusive licenses of Intellectual Property Rights granted by the Company or any of its Subsidiaries or Parent, as applicable, in the Ordinary Course of Business and that do not (in any case or in the aggregate) materially detract from the value of the Intellectual Property Rights subject thereto; and (f) statutory liens in favor of carriers, warehousemen, mechanics and materialmen, to secure claims for labor, materials or supplies.

"***Person***" means any individual, Entity or Governmental Body.

"***Proxy Statement***" means the proxy statement to be sent to Parent's stockholders in connection with the Parent Stockholders' Meeting.

"***Reference Date***" means September 6, 2019.

"***Registered IP***" means all Intellectual Property Rights that are registered or issued under the authority of any Governmental Body, including all patents, registered copyrights, registered mask works, and registered trademarks, service marks and trade dress, and all applications for any of the foregoing.

"***Representatives***" means directors, officers, employees, agents, attorneys, accountants, investment bankers, advisors and representatives.

"***Sarbanes-Oxley Act***" means the Sarbanes-Oxley Act of 2002.

"***SEC***" means the United States Securities and Exchange Commission.

"***Securities Act***" means the Securities Act of 1933, as amended.

"***Series A Preferred Stock***" means the shares of the Series A Preferred Stock of the Company, par value $0.0001 per share.

"***Series B Preferred Stock***" means the shares of the Series B Preferred Stock of the Company, par value $0.0001 per share.

An entity shall be deemed to be a "***Subsidiary***" of a Person if such Person directly or indirectly owns or purports to own, beneficially or of record, (a) an amount of voting securities or other interests in such entity that is sufficient to enable such Person to elect at least a majority of the members of such entity's board of directors or other governing body, or (b) at least 50% of the outstanding equity, voting, beneficial or financial interests in such Entity.

"***Superior Offer***" means an unsolicited bona fide written Acquisition Proposal (with all references to 20% in the definition of Acquisition Transaction being treated as references to greater than 80% for these purposes) that: (a) was not obtained or made as a direct or indirect result of a breach of (or in violation of) this Agreement; and (b) is on terms and conditions that the Parent Board or the Company Board, as applicable, determines in good faith, taking into account at the time of determination all circumstances determined by the Parent Board or the Company Board, as applicable, in good faith to be relevant, including the various legal, financial and regulatory aspects of the Acquisition Proposal, all the terms and conditions of such Acquisition Proposal and this Agreement, any written offer by the other Party to this Agreement to amend the terms of this Agreement in response to such Acquisition Proposal, and the anticipated timing, conditions and the ability of the Person making such Acquisition Proposal to consummate the transactions contemplated by such Acquisition Proposal, and following consultation with its outside legal counsel and outside financial advisors, if any, are more favorable, from a financial point of view, to Parent's stockholders or the Company's stockholders, as applicable, than the terms of the Contemplated Transactions.

"***Takeover Statute***" means any "fair price," "moratorium," "control share acquisition" or other similar anti-takeover Law.

"***Tax***" means any federal, state, local, foreign or other tax, including any income, capital gain, gross receipts, capital stock, profits, transfer, estimated, registration, stamp, premium, escheat, unclaimed property, customs duty, ad valorem, occupancy, occupation, alternative, add-on, windfall profits, value added, severance, property, business, production, sales, use, license, excise, franchise, employment, payroll, social security, disability, unemployment,

workers' compensation, national health insurance, withholding or other taxes, duties, fees, assessments or governmental charges, surtaxes or deficiencies thereof of any kind whatsoever, however denominated, and including any fine, penalty, addition to tax or interest imposed by a Governmental Body with respect thereto.

"***Tax Return***" means any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document, and any amendment or supplement to any of the foregoing, filed with or submitted to, or required to be filed with or submitted to, any Governmental Body in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Law relating to any Tax.

"***Treasury Regulations***" means the United States Treasury regulations promulgated under the Code.

"***WARN Act***" means the Worker Adjustment Retraining and Notification Act of 1988, as amended, or any similar state or local plant closing mass layoff statute, rule or regulation.

(b) Each of the following terms is defined in the Section set forth opposite such term:***

Term	Section
Allocation Certificate	5.15(a)
Anti-Bribery Laws	2.23
Business Associate Agreement	2.14(h)
Certificate of Merger	1.3
Certifications	3.7(a)
Closing	1.3
Closing Date	1.3
Company	Preamble
Company Audited Financial Statements	5.16
Company Benefit Plan	2.17(a)
Company Disclosure Schedule	Section 2
Company Financials	2.7(a)
Company In-bound Licenses	2.12(d)
Company Interim Financial Statements	5.16
Company Lock-Up Agreement	Recitals
Company Material Contract	2.13(a)
Company Out-bound Licenses	2.12(d)
Company Permits	2.14(b)
Company Plan	2.6(c)
Company Preferred Stock	2.6(a)
Company Real Estate Leases	2.11
Company Signatories	Recitals
Company Stock Certificate	1.6
Company Stockholder Written Consent	2.4
Continuing Employee	4.7(a)
Costs	5.5(a)
D&O Indemnified Parties	5.5(a)
D&O Tail Policy	5.5(d)
Determination Notice	5.3(d)(i)
Dissenting Shares	1.8(a)
DLA	5.9(c)
Drug Regulatory Agency	2.14(a)
Effective Time	1.3
End Date	9.1(b)
Exchange Agent	1.7(a)
Exchange Fund	1.7(a)
FDA	2.14(a)

Term	Section
FDCA	2.14(a)
FLSA	2.17(o)
HIPAA	2.14(h)
Intended Tax Treatment	5.9(a)
Investor Agreements	2.22(b)
Liability	2.9
Merger	Recitals
Merger Consideration	1.5(a)(ii)
Merger Sub	Preamble
Nasdaq Fees	5.8
Nasdaq Listing Application	5.8
New Plans	4.7(b)
Other Parent Stockholder Matter	5.3(a)(iv)
Parent	Preamble
Parent Benefit Plan	3.17(a)
Parent Board Adverse Recommendation Change	5.3(c)
Parent Board Recommendation	5.3(c)
Parent Disclosure Schedule	Section 3
Parent In-bound License	3.12(d)
Parent Lock-Up Agreement	Recitals
Parent Material Contract	3.13
Parent Out-bound License	3.12(d)
Parent Permits	3.14(b)
Parent Real Estate Leases	3.11
Parent SEC Documents	3.7(a)
Parent Signatories	Recitals
Parent Stockholder Matters	5.3(a)(iv)
Parent Stockholder Support Agreement	Recitals
Parent Stockholders' Meeting	5.3(a)(iv)
Parent Tax Representation Letters	5.9(c)
Pre-Closing Period	4.1(a)
Required Company Stockholder Vote	2.4
Required Parent Stockholder Vote	3.4
Sensitive Data	2.12(g)
Stockholder Notice	5.2
Surviving Corporation	1.1

EXHIBIT B

FORM OF LOCK-UP

EXHIBIT C

PARENT STOCKHOLDER SUPPORT AGREEMENT

EXHIBIT D

SPECIFIED POST-CLOSING PARENT DESIGNEES

Officers

Name	Title
Rick Hawkins	Chief Executive Officer
Eugene P. Kennedy, MD	Chief Medical Officer
John McKew, PhD	Chief Science Officer
Carl Langren	Chief Financial Officer
Brad Powers, JD	General Counsel
Chris Bemben, MBA	Director, Business Development
Lori Lawley, CPA	VP Finance and Controller

EXHIBIT E

CERTIFICATE OF AMENDMENT
TO THE
AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
LUMOS PHARMA, INC.

(Pursuant to Section 242 of the
General Corporation Law of the State of Delaware)

LUMOS PHARMA, INC. (the "***Corporation***"), a corporation organized and existing under the provisions of the Delaware General Corporation Law (the "General Corporation Law"),

DOES HEREBY CERTIFY:

FIRST. The name of the Corporation is Lumos Pharma, Inc. and that the Corporation was originally converted from a Texas corporation to a Delaware corporation pursuant to the General Corporation Law on January 2, 2014 under the name Lumos Pharma, Inc. An Amended and Restated Certificate of Incorporation of the Corporation was filed with the Secretary of State of the State of Delaware on April 1, 2016 (the "***Amended and Restated Certificate***").

SECOND. This Certificate of Amendment to the Amended and Restated Certificate was duly adopted by the Corporation's Board of Directors and stockholders in accordance with the applicable provisions of Sections 228 and 242 of the General Corporation Law.

THIRD. Article Fourth Section B is hereby amended to include a new Subsection 2.5 as follows:

"2.5 Special Allocation of Assets. Notwithstanding anything in this Certificate of Incorporation to the contrary, upon the closing (the "***Closing***") of that certain Agreement and Plan of Merger and Reorganization, dated as of September [ ], 2019 (the "***Merger Agreement***"), by and among NewLink Genetics Corporation ("***Parent***"), Cyclone Merger Sub, Inc. and the Corporation, (i) each holder of shares of Series B Preferred Stock shall be entitled to be paid a number of shares of Parent Common Stock equal to the product of the Per Share Series B Exchange Ratio, *multiplied by* the number of shares of Series B Preferred Stock held by such holder, (ii) each holder of shares of Series A Preferred Stock shall be entitled to be paid a number of shares of Parent Common Stock equal to the product of the Per Share Series A Exchange Ratio, *multiplied by* the number of shares of Series A Preferred Stock held by such holder, (iii) each holder of shares of Common Stock shall be entitled to be paid a number of shares of Parent Common Stock equal to the product of the Per Share Common Stock Exchange Ratio, *multiplied by* the number of shares of Common Stock held by such holder, and (iv) other than the foregoing, the holders of Common Stock and Preferred Stock shall not be entitled to receive any other payment, including, for the avoidance of doubt, any Accruing Dividends pursuant to Article Fourth, Section B.1 of this Certificate or any payments pursuant to Article Fourth, Sections B.2.1 through B.2.3; *provided*, *however*, that, for the avoidance of doubt, if the Closing does not occur for any reason, this Article Fourth, Section B.2.5 shall be null and void and of no further effect and upon any subsequent voluntary or involuntary liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the provisions of Article Fourth, Sections B.2.1 through B.2.3 shall control.

For purposes of this Article Fourth, Section B.2.5, the following definitions shall apply:

"***Parent Common Stock***" shall mean the common stock, $0.01 par value per share, of Parent.

"***Parent Common Stock Ratio***" shall mean an amount equal to the quotient of (i) 37,312,620, *divided by* (ii) the Company Merger Shares (as defined in the Merger Agreement).

"***Per Share Common Stock Exchange Ratio***" shall mean an amount equal to (i) the quotient of (x) 1.18655352337665, *divided by* (y) the Parent Common Stock Ratio *multiplied by* (ii) the quotient of (x) 8,933,437, *divided by* (y) the aggregate number of Common Stock outstanding at the Closing.

"***Per Share Series A Exchange Ratio***" shall mean an amount equal to (i) the quotient of (x) 0.786153154291732, *divided by* (y) the Parent Common Stock Ratio *multiplied by* (ii) the quotient of (x) 11,204,513, *divided by* (y) the aggregate number of Series A Preferred Stock outstanding at the Closing.

"***Per Share Series B Exchange Ratio***" shall mean an amount equal to (i) the quotient of (x)1.79647182727751, *divided by* (y) the Parent Common Stock Ratio *multiplied by* (ii) the quotient of (x) 9,966,288, *divided by* (y) the aggregate number of Series B Preferred Stock outstanding at the Closing.

FOURTH. This Certificate of Amendment to the Amended and Restated Certificate shall be effective on and as of the date of filing of this Certificate of Amendment with the Secretary of State of the State of Delaware.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, this Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Corporation has been executed by a duly authorized officer of the Corporation this _____ day of_____, 2019.

LUMOS PHARMA, INC.

_____

Richard J. Hawkins
President and Chief Executive Officer

Amendment No. 1 to Agreement and Plan of Merger and Reorganization

This **Amendment No. 1 to Agreement and Plan of Merger and Reorganization** (this "***Agreement***") is made as of November 19, 2019, with respect to that certain Agreement and Plan of Merger and Reorganization, dated as of September 30, 2019 (as amended, the "***Merger Agreement***"), by and among NewLink Genetics Corporation, a Delaware corporation ("***Parent***"), Cyclone Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent ("***Merger Sub***") and Lumos Pharma, Inc., a Delaware corporation (the "***Company***"). Capitalized terms used and not otherwise defined herein shall have the meanings accorded to such terms under the Merger Agreement.

WITNESSETH:

Whereas, Section 10.2 of the Merger Agreement provides that the Merger Agreement may be amended with a written agreement signed by each of the Company, Merger Sub, and Parent (together, the "***Parties***") and the approval of each Party's board of directors; and

Whereas, each Party's board of directors has approved this Agreement.

Now, Therefore, in consideration of the foregoing premises and certain other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto further agree as follows:

1. ***Amendments to Merger Agreement.***

(a) Section 1.4(b) of the Merger Agreement is hereby amended and restated in its entirety as follows:

"(b) the certificate of incorporation of Parent shall be identical to the certificate of incorporation of Parent immediately prior to the Effective Time, until thereafter amended as provided by the DGCL and such certificate of incorporation, *provided*, *however*, that (i) prior to the Effective Time, Parent shall file an amendment to its certificate of incorporation as contemplated by Section 5.3(a)(i), to effect the Nasdaq Reverse Split and (ii) following the Effective Time, Parent shall file another amendment to its certificate of incorporation to change the name of Parent to Lumos Pharma, Inc., and make such other changes as are mutually agreeable to Parent and the Company;"

(c) Section 5.11 of the Merger Agreement is hereby amended and restated in its entirety as follows:

"**Directors and Officers**.

(a) The Parties shall use reasonable best efforts and take all necessary action so that immediately after the Effective Time, (i) the Parent Board is comprised of six members, with (A) three such members designated by Parent and (B) three such members designated by the Company, and (ii) the Persons listed in Exhibit D under the heading "Officers" are elected or appointed, as applicable, to the positions of officers of Parent, as set forth therein, to serve in such positions effective as of the Effective Time until successors are duly appointed and qualified in accordance with applicable Law. If any Person listed in Exhibit D is unable or unwilling to serve as an officer of Parent or the Surviving Corporation, as set forth therein, as of the Effective Time, the Parties shall mutually agree upon a successor.

(b) After the Closing, (i) a seventh member of the Parent Board shall be unanimously appointed by the other directors of the Parent Board as soon as reasonably practicable, and (ii) thereafter, the nominating committee of the Parent Board shall nominate the directors of Parent in the ordinary course."

(c) Section 5.1(a) of the Merger Agreement is hereby amended and restated in its entirety as follows:

"(a) As promptly as practicable after the date of this Agreement (but in no event later than fifty-three (53) days following the date of this Agreement), the Parties shall prepare and cause to be filed with the SEC a preliminary Proxy Statement. Following (i) confirmation by the SEC that it has no further comments or (ii) expiration of the 10-day waiting period contemplated by Rule 14a-6(a) promulgated under the Exchange Act, Parent shall use commercially reasonable efforts to cause the Proxy Statement in definitive form to be mailed to the stockholders of Parent."

(d) The notice information with respect to the Company, starting with the words "if to the Company:", in Section 10.8 of the Merger Agreement is hereby amended and restated in its entirety as follows:

"if to the Company:

Lumos Pharma, Inc.
4200 Marathon Blvd., Suite 200
Austin, Texas 78756
Attention: Rick Hawkins, President & Chief Executive Officer
Email: rhawkins@lumos-pharma.com

with a copy to (which shall not constitute notice):

Wilson Sonsini Goodrich & Rosati P.C.
900 South Capital of Texas Highway
Las Cimas IV, Fifth Floor
Austin, Texas 78746
Attn.: J. Robert Suffoletta
Email: rsuffoletta@wsgr.com"

2. ***Continuing Effectiveness***. Except as expressly modified by this Agreement, the Merger Agreement shall remain in full force and effect in accordance with its terms. This Agreement shall be deemed an amendment to the Merger Agreement and shall become effective when executed and delivered by the Parties. Upon the effectiveness of this Agreement, all references in the Merger Agreement to "the Agreement" or "this Agreement," as applicable, shall refer to the Merger Agreement, as modified by this Agreement.

3. ***Counterparts***. Except as specifically modified herein, the Merger Agreement remains in full force and effect. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, with the same effect as if the signatures thereto were in the same instrument. The exchange of a fully executed Amendment (in counterparts or otherwise) by the Parties by electronic transmission in .PDF format shall be sufficient to bind the Parties to the terms and conditions of this Amendment.

4. ***Miscellaneous***. Sections 10.5 (Applicable Law; Jurisdiction; Waiver of Jury Trial), 10.7 (Assignability), 10.10 (Severability), 10.11 (Other Remedies; Specific Performance), 10.12 (No Third Party Beneficiaries) and 10.13 (Construction) are incorporated by reference herein, mutatis mutandis, as if set forth at length herein.

[*remainder of page intentionally left blank*]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date first written above.

NEWLINK GENETICS CORPORATION

/s/ Brad Powers

By: Brad Powers
Its: Office of the Chief Executive Officer

CYCLONE MERGER SUB, INC.

/s/ Brad Powers

By: Brad Powers
Its: President

LUMOS PHARMA, INC.

/s/ Richard J. Hawkins

By: Richard J. Hawkins
Its: President and Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**
For the fiscal year ended December 31, 2018.

o **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**
For the transition period from to .
Commission File Number
001-35342

NEWLINK GENETICS CORPORATION
(Exact name of Registrant as specified in Its Charter)

Delaware	**42-1491350**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2503 South Loop Drive
Ames, Iowa 50010
(515) 296-5555
(Address, including zip code, and telephone number, including area code, of principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.01	**The Nasdaq Global Market**
Securities registered pursuant to Section 12(g) of the Act:	**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ☒

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and emerging growth company in Rule 12b-2 of the Exchange Act:

Large accelerated filer o	Accelerated filer ☒
Non-accelerated filer o	Smaller reporting company ☒
	Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant based on the closing sale price of the registrant's common stock on June 30, 2018, as reported by the NASDAQ Global Market, was $137,519,199. Shares of the registrant's common stock beneficially owned by each executive officer and director of the registrant and by each person known by the registrant to beneficially own 10% or more of its outstanding common stock have been excluded, in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily conclusive.

As of February 27, 2019, there were 37,276,102 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference to our definitive Proxy Statement for our 2018 Annual Meeting of Stockholders.

NewLink Genetics Corporation

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Part I

Part II

Signatures

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and such statements are subject to the "safe harbor" created by those sections. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "contemplate," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements regarding the following: our plans to develop and commercialize our product candidates; our ongoing and planned preclinical studies and clinical trials; the timing of release of the results of interim analyses or other data from ongoing clinical studies; the timing for completion of enrollment and outcomes of our ongoing clinical studies; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the clinical utility of our product candidates; our plans to leverage our existing technologies to discover and develop additional product candidates; our ability to quickly and efficiently identify and develop product candidates; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property position; the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and other risks and uncertainties, including those listed under the caption "Risk Factors."

The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. These statements involve known and unknown risks and uncertainties that may cause our, or our industry's results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among other things, those discussed under the captions "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements not specifically described above also may be found in these and other sections of this report.

We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so, even if new information becomes available, except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. You are also advised to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q, and our Current Reports on Form 8-K.

PART I

Item 1. BUSINESS

Overview

NewLink Genetics Corporation (the "Company", "NewLink", "we", "our" or "us") is a clinical-stage immuno-oncology company focused on developing novel immunotherapeutic products for the treatment of patients with cancer. Our leading small-molecule product candidates currently in clinical development target the indoleamine-2, 3-dioxygenase, or IDO, pathway, which is one of the key pathways for cancer immune escape. These product candidates, indoximod and NLG802 (a prodrug of indoximod), are IDO pathway inhibitors with mechanisms of action that center around breaking the immune system's tolerance to cancer. We also have an additional small molecule product candidate, NLG207, which is a nanoparticle-drug conjugate, or NDC, consisting of a cyclodextrin-based polymer backbone linked to camptothecin, a topoisomerase 1 inhibitor of the topoisomerase-1 inhibitor, camptothecin.

In cancer, the IDO pathway regulates immune response by suppressing T-cell activation, which enables cancer to avoid immune response. IDO is overexpressed in many cancers, both within tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor-draining lymph nodes, thereby promoting peripheral tolerance to tumor associated antigens, or TAAs. When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system.

The IDO pathway refers to a series of reactions initiated by IDO that result in the reduction of the amino acid tryptophan in the local tumor environment. We believe the local presence of tryptophan in adequate concentrations promotes antitumor T-cells, and the local reduction of tryptophan combined with the presence of the break-down product of tryptophan metabolism, kynurenine, is understood to suppress the activation of T-cells. Preclinical and, increasingly, clinical data suggest that IDO pathway inhibitors may also enhance the anti-tumor effects of other immunotherapies, chemotherapies and radiation when used as a combination therapy for patients with cancer.

We had a net loss of $53.6 million for the year ended December 31, 2018. We expect to continue to have losses for the foreseeable future as we advance our product candidates through clinical trials, pursue regulatory approval of our product candidates, and prepare for one or more of our product candidates receiving marketing approval.

Founded in 1999, our principal executive office is located Ames, Iowa, with additional offices located in Austin, Texas and Wayne, Pennsylvania. We have clinical, research and development staff dedicated to our pipeline of product candidates for patients with cancer and other diseases.

Our Strategy

Our strategy is to develop and commercialize immunotherapeutic products for the treatment of patients with cancer where there are unmet needs with current therapies. The critical components of our business strategy in 2019 include:

- Advance the clinical development of indoximod in diffuse intrinsic pontine glioma, or DIPG, recurrent pediatric brain tumors, or rPBT, and acute myeloid leukemia, or AML;
- Progress forward the clinical development of NLG207 for patients with recurrent ovarian cancer as well as advancing chemistry, manufacturing, and control, or CMC, development activities;
- Advance the clinical development of NLG802, a prodrug of indoximod with the potential for a multi-fold increase in drug exposure compared to the base formulation, in multiple cancer indications;
- Analyze the potential for the clinical development of indoximod in programmed cell death-1, or PD-1, refractory melanoma; and
- Evaluate outside opportunities for in-licensing or strategic acquisition to expand our pipeline and leverage current clinical development and financial resources.

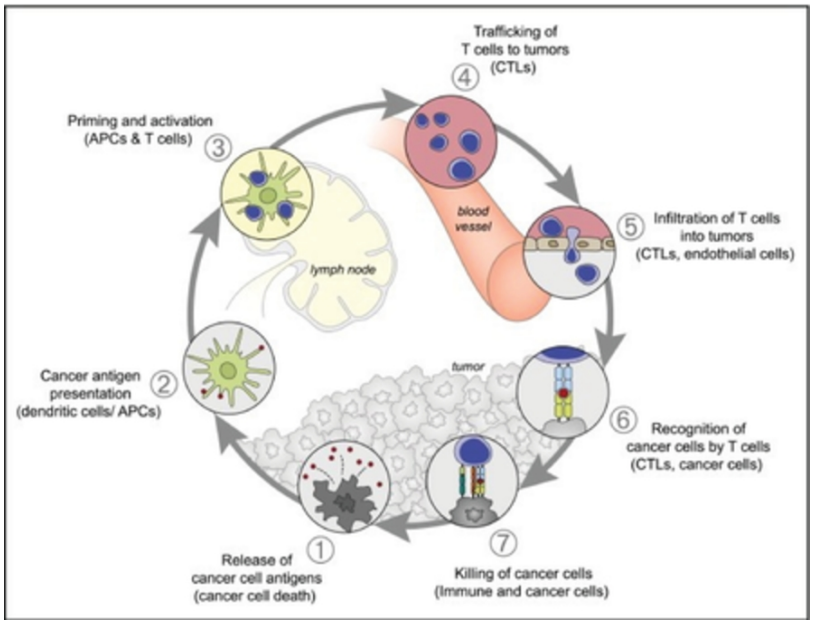
We plan to present the following updates to our clinical trials during 2019:

- Final results for the Phase 2 Clinical Study of NLG207, a nanoparticle formulation of the topoisomerase-1 inhibitor, camptothecin, in combination with weekly paclitaxel in for patients with recurrent ovarian cancer;

- Updated data from the efficacy portion of the Phase 1b clinical study of indoximod plus radiotherapy for pediatric patients with DIPG;
- Updated data from a Phase 1 study of NLG802; and
- Updated Phase 1b clinical data for indoximod plus standard-of-care radio-chemotherapy for pediatric patients with recurrent malignant brain tumors.

IDO Pathway Inhibitors

We have a clinical development program focused on the IDO pathway. Our small-molecule IDO pathway inhibitor product candidates currently in clinical development include indoximod and NLG802. Our product candidates are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. Indoximod acts as a tryptophan mimetic, thereby signaling the activation of antitumor T-cells by the up regulation of mTOR, acts directly on T-cells, and modulates AhR-mediated effects.



We have observed an encouraging safety profile for our IDO pathway inhibitors. They are also orally bioavailable and we believe they offer the potential to be synergistic with other therapies such as radiation, chemotherapy, vaccination and immunotherapies involving other checkpoint inhibitors such as anti-PD-1, anti-programmed cell death ligand-1, or PD-L1, or anti-cytotoxic T-lymphocyte antigen 4, or CLTA4. Clinical data suggest an increase in clinical activity without adding significant toxicity.

Indoximod

Indoximod, our lead IDO pathway inhibitor, is currently in clinical development in combination with other cancer therapeutics for patients with DIPG, pediatric brain tumors, acute myeloid leukemia, and melanoma. We believe there may be additional opportunities to apply indoximod to a broader set of cancer indications. Indoximod has been studied in more than 800 patients to date and has been generally well-tolerated, including in combination with PD-1 checkpoint inhibitors, various chemotherapy agents, radiation, and a cancer vaccine.

A tablet formulation of indoximod hydrochloride, or indoximod salt, has been developed for adult patients and a sprinkle formulation is being developed for pediatric indications. We plan to use our new tablet formulation of indoximod in future clinical trials.

Two U.S. patents covering both the salt and prodrug formulations of indoximod were issued in the U.S. on August 15, 2017 and February 19, 2019 providing exclusivity until at least 2036. We are currently pursuing international patent coverage for these formulations.

NLG207

NLG207 is an NDC consisting of a cyclodextrin-based polymer backbone linked to camptothecin, a topoisomerase-1, or top-1, inhibitor. Because the vasculature in tumors is more permeable than normal tissue, we believe NDCs have the potential to enhance drug delivery to tumors by enabling gradual payload release inside cancer cells to augment antitumor activity while reducing off-target toxicity. NLG207 is currently being studied in single agent and in combination with paclitaxel in recurrent ovarian, fallopian tube or primary peritoneal cancer.

NLG802

NLG802 is a prodrug of indoximod. NLG802 is intended to increase bioavailability and exposure to indoximod above levels currently achievable by direct oral administration of indoximod. We filed an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA, in the first quarter of 2017 and the first patient was dosed with NLG802 in a Phase 1 clinical trial in July 2017. The purpose of this Phase 1 trial is to assess preliminary safety and to determine the recommended dose for subsequent Phase 2 evaluations. NLG802 is a new chemical entity with patent coverage into 2036. We are also pursuing international patent coverage for NLG802.

NLG919

NLG919, a direct enzymatic inhibitor, was previously in clinical development as part of our collaboration with Genentech, Inc., or Genentech. In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech, or the Genentech Agreement. The Genentech Agreement provided for the development and commercialization of NLG919. On December 6, 2017, the Genentech Agreement with respect to NLG919 terminated. As part of the partial termination, worldwide rights to NLG919 reverted to us and Genentech granted us a license under certain of Genentech's intellectual property to develop and commercialize NLG919. We continue to explore the potential for further development and licensing opportunities but do not have an active program for the drug product candidate as of December 31, 2018.

Under the Genentech Agreement, we conducted a two-year pre-clinical research program with Genentech to discover novel next generation IDO/tryptophan-2,3-dioxygenase, or TDO, inhibitors. The research program ended in November 2016, and we received notice on May 9, 2018 that Genentech would not continue the collaboration with respect to next generation IDO/TDO inhibitors identified through the research program. The Genentech Agreement terminated in its entirety on November 6, 2018 and we received control of the intellectual property portfolio related to the newly discovered TDO inhibitors, IDO inhibitors and dual IDO/TDO inhibitors.

Ebola Vaccine Candidate

In November 2014, we entered into an exclusive, worldwide license and collaboration agreement, or the Merck Agreement, with Merck, Sharpe and Dohme Corp., or Merck, to develop and potentially commercialize our rVSVΔG-ZEBOV GP vaccine product candidate and other aspects of our vaccine technology. The rVSVΔG-ZEBOV GP vaccine product candidate was originally developed by the Public Health Agency of Canada, or PHAC, and is designed to utilize the rVSV vector to induce immunity against Ebola virus when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. Under the Merck Agreement, we received an upfront payment of $30.0 million in October 2014, and in February 2015 we received a milestone payment of $20.0 million. We have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved by the FDA and successfully commercialized by Merck. rVSVΔG-ZEBOV GP is also eligible to receive a priority review voucher and we are entitled to a portion of the value of the voucher if it is granted. In addition to milestone payments from Merck, we were awarded contracts for development of the rVSVΔG-ZEBOV GP from the U.S. BioMedical Advanced Research & Development Authority, or BARDA, and the Defense Threat Reduction Agency, or DTRA, totaling $52.1 million during 2016 and $67.0 million during 2014 and 2015. Funds of $2.1 million were de-obligated from the DTRA grant awards in 2017. We have received total awards of $118.8 million.

On April 26, 2018 we entered into an agreement with Merck, DTRA and BARDA to transfer the government grants from BARDA and DTRA to Merck. The transfer was completed in June 2018 and Merck has replaced us as the prime contractor on all such grants.

Cancer Market Overview

Cancer is the second-leading cause of death in the United States; the American Cancer Society estimated that more than 600,000 deaths will occur in 2019 and almost 1.7 million new cancer cases are expected to be diagnosed

in 2019. Despite a number of advances in the diagnosis and treatment of cancer over the past decade, overall five-year survival rates from all cancer types is 63% for the period spanning 2008-2014 according to the National Cancer Institute.

Cancer is characterized by abnormal cells that grow and proliferate, forming masses called tumors. Under certain circumstances, these proliferating cells can metastasize, or spread, throughout the body and produce deposits of tumor cells called metastases. As the tumors grow, they may cause tissue and organ failure and, ultimately, death. To be effective, cancer therapies must eliminate or control the growth of the cancer.

The specialized cells of the immune system recognize specific chemical structures called antigens. Generally, foreign antigens trigger an immune response that results in the removal of disease-causing agents from the body. Cancer cells, however, frequently display antigens that are also found on normal cells. The immune system may not be able to distinguish between tumors and normal cells and therefore may be unable to mount a strong anti-cancer response. Additionally, tumors often express abnormal proteins that could be recognized by the immune system. However, tumors also have various immune-suppressive defense mechanisms that may prevent the immune system from fully activating and recognizing these abnormal antigens.

Current therapies, such as surgery, radiation, hormone treatments and chemotherapy, do not directly address this immune-evasive characteristic of cancer and may not have the desired therapeutic effect. Active immunotherapies stimulate the immune system, the body's natural mechanism for fighting disease, and may overcome some of the limitations of current standard-of-care cancer therapies.

Limitations of Current Cancer Therapies

We believe current cancer treatment alternatives suffer from a number of limitations that impair their effectiveness including:

- *Toxicity.* Chemotherapeutic agents are highly toxic to the human body and often cause a variety of side effects, which may include nausea and vomiting, bleeding, anemia and mucositis. Targeted therapeutics may have fewer systemic toxicities, but still tend to have off-target effects such as gastrointestinal inflammation, severe skin reactions and breathing difficulties. These effects limit a patient's ability to tolerate treatment thereby depriving the patient of the potential benefit of additional treatments or treatment combinations that might otherwise destroy or prevent the growth of cancer cells. Once educated as to the limited efficacy, limited increased survival and potentially significant toxicity of existing treatment alternatives, patients diagnosed with terminal cancer often choose to limit or forego therapy in order to avoid further compromising their quality of life. Patients with advanced stage cancer often cannot tolerate cancer therapy, and certain therapies have been shown to hasten death in some cases as the patient's health deteriorates.
- *Development of resistance.* While many current therapeutic approaches may be effective against a particular target, the overall impact of these therapies on treating cancer is limited because the abundance and diversity of tumor cells are believed to enable cancers to adapt and become resistant to these treatments over time resulting in reduced longer-term efficacy.
- *Short-term approach.* Incremental survival benefit is the primary objective of many currently marketed and development-stage cancer therapeutics. In general, many drugs show modest impact on overall survival or only affect progression-free survival. Other than surgical tumor removal, curative intent is often not a focus or realistic potential outcome of many current cancer therapies.
- *Immune system suppression.* Cancer is difficult to treat in part because cancer cells use sophisticated strategies to evade the immune system. Cancer treatment often involves the introduction of an agent, such as a chemical, an antibody or radiation, which causes cell apoptosis (programmed cell death) or inhibit the proliferation of all cells, including immune cells, thereby indirectly suppressing the immune system. A weakened immune system not only further inhibits the body's natural ability to fight cancer, but also causes patients to become more susceptible to infections and other diseases.

Grants and Contracts with the United States Government

Other than the upfront payments received in 2014 from Genentech and Merck, grants and contracts with the United States Government accounted for substantially all of our revenue in each of the last four fiscal years. As the prime contractor for BARDA, since December 2014, we have been awarded a total of approximately $103.0 million

in funding and approximately $51.0 million of additional contract options to support the manufacturing and development activities of our Ebola vaccine product candidate. Activities included clinical development through a 330-person Phase 1b clinical trial, the scale-up of the manufacturing process related to our Ebola vaccine product candidate, and the development of the investigational rVSVΔG-ZEBOV GP vaccine candidate, designated V920, designed to induce immunity against the Ebola Zaire virus. The funding supported manufacturing facility readiness, manufacturing process qualification activities, and additional clinical trials to support regulatory approval of the V920 vaccine currently being led by our partner, Merck.

We have also received funding from the United States Department of Defense to support the development of contract manufacturing for the vaccine product candidate for clinical trials. Since 2014, we have been awarded funds of approximately $15.6 million to support various development activities of our Ebola vaccine product candidate.

Manufacturing

We currently contract with manufacturing organizations to develop and manufacture the novel formulations for indoximod, NLG802, and NLG207. We believe that many suppliers would be available for the production of these product candidates, if required. We currently have no plans to build our own manufacturing facility to support any of these product candidates.

If we were to need additional supply of NLG919, we would be responsible for the manufacturing and would seek to contract with manufacturing organizations to develop and manufacture NLG919. We currently have no plans to build our own manufacturing facility to support this product candidate.

Merck has assumed responsibility for manufacturing the Ebola vaccine product candidate in accordance with the Merck Agreement.

Sales and Marketing

We currently own exclusive worldwide commercial rights to all our product candidates other than the Ebola vaccine candidate. In the future, we may build a commercial infrastructure to support any of these products, should they receive FDA or other applicable regulatory authorization. In addition, we may pursue collaborations or co-promotion arrangements with pharmaceutical and biotechnology companies to complement these efforts or for particular indications or in specific territories.

Competition

The biopharmaceutical industry is highly competitive. Given the significant unmet patient need for new therapies, oncology is an area of focus for many public and private biopharmaceutical companies, public and private universities and research organizations actively engaged in the discovery and research and development of products for cancer. As a result, there are and will likely continue to be extensive research and substantial financial resources invested in the discovery and development of new oncology products. In addition, there are a number of multinational pharmaceutical companies and large biotechnology companies currently marketing or pursuing the development of products or product candidates targeting the same cancer indications as our product candidates.

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drugs, obtaining FDA and other regulatory approvals, and the commercialization of those products. Accordingly, our competitors may be more successful in obtaining approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

We also face competition from pharmaceutical and biotechnology companies, academic institutions, government agencies and private research organizations in recruiting and retaining highly qualified scientific personnel and consultants and developing and acquiring technologies, obtaining patent protection, and securing sufficient capital resources for the often lengthy period between technological conception and commercial sales. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, thereby preventing us from obtaining technology on commercially reasonable terms, if at all. We will also compete

for the services of third parties that may have already developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies to target the diseases on which we have focused both inside and outside of the United States.

Immunotherapy Products for Cancer

The cancer immunotherapy landscape is broad but still in the early stages of development as compared to more established approaches like cytotoxic chemotherapy. Several immunotherapy products to treat cancer been approved in recent years. Multiple drugs classified as checkpoint inhibitors have been approved since 2011 targeting either CTLA-4, PD-1 or PDL-1 via antibody blockade. Additionally, there have been regulatory approvals for other immunotherapies in the classes of CAR-T and oncolytic virus. The indications for which these agents have been approved include some indications that we are pursuing or plan to pursue in our clinical development. Other indications in our clinical development plan, such as malignant brain tumors and AML, do not currently have any FDA approved immunotherapies for immune checkpoint inhibitors.

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies, firms specialized in the development and production of vaccines, checkpoint inhibitors, and other immunotherapies, and major universities and research institutions. Many companies are developing or commercializing products in areas that we have targeted for product development. Some of these products use therapeutic approaches that may compete directly with our product candidates. Most of our competitors possess substantially greater financial, technical and human resources than we possess. In addition, many of our competitors have significantly greater experience than we have in conducting preclinical and nonclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of drugs and manufacturing facilities. We are also facing increasing competition in enrolling patients in our clinical trials. Accordingly, our competitors may succeed in obtaining regulatory approval for drugs more rapidly than we do. If we obtain regulatory approval and launch commercial sales of our product candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

Strategic Collaborations

Genentech Agreement

In October 2014, we entered into the Genentech Agreement for the development and commercialization of NLG919, our clinical stage IDO pathway inhibitor, and a research collaboration for the discovery of next generation IDO/TDO inhibitors to be developed and commercialized under the Genentech Agreement. Under the terms of the Genentech Agreement, we received an upfront non-refundable payment of $150.0 million in 2014 and funding for our participation in the research collaboration, which ended in November 2016.

The agreement was terminated in part on December 6, 2017 and the rights to NLG919 reverted back to us. As part of the partial termination, Genentech granted to us an exclusive license to certain intellectual property of Genentech, to develop and commercialize NLG919, and we are obligated to pay to Genentech a royalty on future net sales of NLG919 in the low single digits. We continue to explore the potential for further development and licensing opportunities but do not have an active program for the drug product candidate as of December 31, 2018.

Under the Genentech Agreement, we conducted a two-year pre-clinical research program with Genentech to discover novel next generation IDO/tryptophan-2,3-dioxygenase, or TDO, inhibitors. The research program ended in November 2016, and we received notice on May 9, 2018 that Genentech would not continue the collaboration with respect to next generation IDO/TDO inhibitors identified through the research program. The Genentech Agreement terminated in its entirety on November 6, 2018.

Merck Agreement

In November 2014, we entered into the Merck Agreement to research, develop and potentially commercialize our Ebola vaccine product candidate and certain other aspects of our vaccine technology. The Ebola vaccine product candidate was originally developed by PHAC. Under the Merck Agreement, we received an upfront payment of $30.0 million in 2014 and a milestone payment of $20.0 million in 2015, and we have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved and if Merck successfully commercializes it. In July 2015, we announced that the international partnership studying the rVSVΔG-ZEBOV GP (Ebola) vaccine

candidate in Guinea released interim data suggesting that it is effective in the prevention of Ebola in a large Phase 3 clinical trial. The rVSVΔG-ZEBOV GP product candidate will continue to be studied in clinical trials. In February 2017 the final report from the trial confirmed that rVSVΔG-ZEBOV GP offers substantial protection against Ebola virus disease, with no cases among vaccinated individuals without the infection from day 10 after vaccination in both randomized and non-randomized clusters.

Under the terms of the Merck Agreement, Merck is granted the exclusive rights to the Ebola vaccine product candidate. The Ebola vaccine product candidate is under a licensing arrangement with BioProtection Systems Corporation, or BPS, our wholly owned subsidiary and a licensee of PHAC. Under these license arrangements, PHAC retains non-commercial rights pertaining to the vaccine candidate. The Merck Agreement was amended on December 5, 2017 in connection with our entry into an amended and restated PHAC license on December 5, 2017. The amended Merck Agreement absolves BPS from any future obligation to negotiate or amend the terms of the PHAC license, converts the scope of Merck's sublicense under PHAC's intellectual property rights to be non-exclusive in the Ebola Sudan field of use, and requires Merck to reimburse us in certain circumstances where we may be obligated to pay royalties to PHAC as a result of Merck's product sales but Merck would not otherwise be obligated to pay a royalty to us.

On April 26, 2018 we entered into an agreement with Merck, DTRA and BARDA to transfer the government grants from BARDA and DTRA to Merck. The transfer was completed in June 2018 and Merck has replaced us as the prime contractor on all such grants. Merck has begun the submission of a rolling Biologics License Application, or BLA, to the U.S. Food and Drug Administration, or FDA, for V920 under the FDA's Breakthrough Therapy Designation for V920. The approval of V920 by the FDA would trigger the issuance of a priority review voucher owned by Merck and in which we may have a substantial economic interest. Thereafter, we would have the right to monetize our share of interest in the voucher.

Unless earlier terminated, the Merck Agreement will continue in effect for as long as Merck has royalty payment obligations to us. Merck may terminate the Merck Agreement for convenience upon a specified period of notice or for certain safety reasons with immediate effect. In the event of Merck's uncured material breach of its obligations under the Merck Agreement with respect to a particular product, we may terminate the Merck Agreement with respect to that product. We may also terminate the Merck Agreement with respect to certain products in the event Merck pursues an alternate product under certain circumstances. Each party may terminate the Merck Agreement for the other party's bankruptcy or insolvency.

Intellectual Property

We believe that patent protection and trade secret protection are important to our business and that our future success will depend, in part, on our ability to maintain our technology licenses, maintain trade secret protection, obtain and maintain patents and operate without infringing the proprietary rights of others both in the United States and abroad. We believe that obtaining identical patents and protection periods for a given technology throughout all markets of the world will be difficult because of differences in patent laws. In addition, the protection provided by non-U.S. patents, if any, may be weaker than that provided by U.S. patents. We have established and continue to build proprietary positions for our IDO pathway inhibitor technology and our NLG207 nanoparticle drug conjugate technology in the United States and abroad. As of March 5, 2019, our patent portfolio included ten patent families relating to our IDO pathway inhibitor technology and four patent families relating to NLG207.

Our IDO pathway inhibitor technology patent portfolio contains several key U.S. patent families that protect indoximod, NLG802, and NLG919. A series of patents covering indoximod were exclusively licensed from Augusta University Research Institute, formerly known as Georgia Regents Research Institute, Georgia Health Sciences University Research Institute, Inc. and the Medical College of Georgia Research Institute. The first patent family contains two issued U.S. patents expiring in 2019 and 2021 including claims to pharmaceutical compositions of 1-methyl-tryptophan (US 8,198,265). The second patent family contains four issued U.S. patents directed to pharmaceutical compositions of indoximod (US 8,232,313, expires in 2024) and to methods of using indoximod to treat cancer (US 7,598,287, US 8,580,844 and US 9,463,239 expires in 2027, 2025, and 2024, respectively). In addition, we have two granted US patents (US 9,732,035 and US 10,207,990) and worldwide pending patent applications covering indoximod prodrugs and novel formulations of indoximod (PCT/US2016/035391). We currently have granted non-U.S. patents covering indoximod prodrugs and novel formulations of indoximod in Singapore. We cannot, however, ensure that we will be able to secure any similar patent grants in other jurisdictions.

We believe that significant barriers to entry in the IDO space are provided by a patent family covering compositions of matter and methods of use of different classes of IDO inhibitor compounds, and are fully owned by us: PCT/US2012/033245, which covers the IDO inhibitor compound NLG919. The national counterparts of the third family provide protection at least until 2032, not counting any patent term adjustment in the United States. This patent has been granted in the United States, Europe, Australia, China, Israel, Japan, Mexico, Hong Kong, Indonesia, Peru, Russia, Chile, Colombia, and New Zealand with multiple applications pending in other countries. An additional application claiming methods of synthesis of NLG919 and related compounds is currently pending (PCT/US2018/024127).

We have also added to our portfolio new patent applications claiming IDO inhibitors, TDO inhibitors and dual IDO/TDO inhibitors derived from our two-year research and collaboration effort with Genentech. These pending patent families are represented by their international applications PCT/CN2016/111730, PCT/US2018/038508, and PCT/US2018/039880.

Additional barriers to entry are provided through exclusive licenses with the Lankenau Institute for Medical Research, or LIMR, and various NewLink-owned inventions, in which we are pursuing patent protection for specific combination therapies targeting the IDO pathway, as well as protection for novel families of inhibitor compounds and second generation products. One patent family that covers methods of treatment of cancer have been licensed from LIMR and are represented by several international issued patents US 8,008,281, EP 2260846, JP 4921965, CN ZL200480014321.1, CA 2520172, US 8,383,613.

Our NLG207 (formerly CRLX101) nanoparticle drug conjugate technology patent portfolio is represented by four main patent families. The main patent family claims compositions and methods of manufacturing of cyclodextrin-based polymers covalently linked to therapeutic agents for delivering the therapeutic agents to tumors, whereby the therapeutic agent is camptothecin or taxanes. This main patent family was exclusively licensed from Cerulean Pharma, Inc. by our fully owned subsidiary Bluelink Pharmaceuticals, Inc., or Bluelink, to research, develop and commercialize NLG207 (along with a separate investigational product) as of March 19, 2017, and is represented by sixteen US granted patents expiring between 2023 and 2024 (US 7270808, US 8110179, US 8252276, US 8314230, US 8389499, US 8399431, US 8404662, US 8475781, US 8518388, US 8580244, US 8580242, US 8580243, US 8603454, US 8609081, US 8680202 and US 9550860), and by 58 granted international patents expiring in 2023 as well as by small number of US and international pending applications. In March of 2017, Cerulean Pharma Inc., sold its rights in the main patent family to Novartis, subject to Bluelink's continuing exclusive license in respect of NGL207 (and the second investigational product). The second patent family, owned by Bluelink and expiring in 2030, claims methods of use of cyclodextrin-containing polymer conjugated with camptothecin and is represented by nine granted international patents (Australia, Belgium, Switzerland, Germany, France, United Kingdom, Japan, Mexico) and pending applications in the United States, Brazil, India, Japan, Hong Kong and Mexico. A third patent family, wholly owned by Bluelink and expiring in 2034, claims methods of use of NLG207 in combination with radiation, and is represented by one granted patent in Europe (EP 3049078) and a pending application in US. A fourth patent family wholly owned by Bluelink and expiring in 2037, claims the use of cyclodextrin-containing polymer conjugated with camptothecin in combination with IDO and TDO inhibitors (PCT/US2017/ 064339).

In order to protect the confidentiality of our technology, including trade secrets and know-how and other proprietary technical and business information, we require all of our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the use or disclosure of confidential information. The agreements also oblige our employees, consultants, advisors and collaborators to assign or license to us ideas, developments, discoveries and inventions made by such persons in connection with their work with us. We cannot be sure that these agreements will maintain confidentiality, will prevent disclosure, or will protect our proprietary information or intellectual property, or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry is highly competitive and patents have been applied for by, and issued to, other parties relating to products or new technologies that may be competitive with those being developed by us. Therefore, any of our product candidates may give rise to claims that it infringes the patents or proprietary rights of other parties now or in the future. Furthermore, to the extent that we, our consultants, or manufacturing and research collaborators, use intellectual property owned by others in work performed for us, disputes may also arise as to the rights to such intellectual property or in related or resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties.

A license required under any such patents or proprietary rights may not be available to us, or may not be available on acceptable terms. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that we are prevented from the development, manufacture or sale of products requiring such licenses. In addition, we could incur substantial costs in defending ourselves in legal proceedings instituted before patent and trademark offices in the United States, the European Union, or other ex-U.S. territories, or in a suit brought against us by a private party based on such patents or proprietary rights, or in a suit by us asserting our patent or proprietary rights against another party, even if the outcome is not adverse to us.

Licensing Agreements

IDO Pathway Inhibitor Technology

The following licensing agreement covers technologies and intellectual property rights related to our IDO pathway inhibitor technology and product candidates:

Augusta University Research Institute License Agreement

We are a party to a License Agreement dated September 13, 2005, or the AURI IDO Agreement, with Augusta University Research Institute, or AURI, which was formerly known as Georgia Regents Research Institute, the Georgia Health Sciences University Research Institute, Inc. and the Medical College of Georgia Research Institute. The AURI IDO Agreement was amended on March 28, 2006, April 27, 2006, February 13, 2007, July 12, 2013, July 10, 2014, and March 15, 2016. The AURI IDO Agreement grants us, including our affiliates, an exclusive, worldwide license, under specified AURI patent rights and related technology to make, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology in all medical applications.

Our license from AURI is subject to AURI's retained right to use, and to permit its academic research collaborators to use, such AURI patent rights and technology for research and educational purposes. In addition, the license is subject to certain rights of and obligations to the U.S. government under applicable law, to the extent that such intellectual property was created using funding provided by a U.S. federal agency. We may grant sublicenses under such license, subject to the prior approval of AURI, not to be unreasonably withheld or delayed.

In consideration of such license grant, we are obligated to pay to AURI specified license fees (including issuing shares of our common stock), annual license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $2.8 million per licensed product (which, as a result of the March 15, 2016 amendment, includes certain prodrugs of indoximod), and royalties as a single-digit percentage of net sales of the licensed products, subject to minimum royalty payments and royalty rates depending on the type of license product. In addition, if we grant a sublicense under the license granted by AURI, we must pay to AURI a percentage of the consideration we receive from the sublicensee. We made a milestone payment of $1.0 million in connection with the March 15, 2016 amendment the AURI IDO Agreement.

If we fail to develop the licensed products in a non-cancer field, specifically infectious disease or diagnostics, AURI may convert our license in such field to a non-exclusive license.

Unless terminated earlier, the AURI IDO Agreement will remain in effect until the expiration of the last licensed AURI patents. Pending the status of certain patent applications and the payment of appropriate maintenance, renewal, annuity or other governmental fees, we expect the last patent will expire under this agreement in 2027, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license. AURI may terminate this agreement for our uncured material breach, bankruptcy or similar proceedings. We may terminate this agreement for AURI's uncured material breach or upon written notice to AURI. For a period of one year following the termination of the agreement, we may sell our licensed products that are fully manufactured and part of our normal inventory at the date of termination. We have the right to assign the AURI Agreement to our affiliates or in connection with the transfer of all or substantially all of our assets relating to the agreement, but any other assignment requires the prior written consent of AURI.

Vaccines for the Biodefense Field

The following licensing agreement to which BPS is a party covers technology and intellectual property rights applicable to BPS's development of vaccines for the biodefense field:

Public Health Agency of Canada License Agreement

BPS is a party to a license agreement with PHAC, dated May 4, 2010, which was amended and restated on December 5, 2017, or the PHAC License. Under the terms of the PHAC License, BPS has a worldwide, personal, non-transferable, sole, revocable, royalty-bearing license under specified patent rights and know-how, for the development and commercialization of products directed to the prevention, prophylaxis and treatment of Ebola (Zaire), a rVSV based on viral hemorrhagic fever, or VHF virus, and a worldwide, personal, non-transferable, non-exclusive, revocable, royalty-bearing license, under specified patent rights and know-how, for the development and commercialization of products directed to the prevention, prophylaxis and treatment of Ebola (Sudan), a VHF virus. The license granted to BPS is subject to Canada's retained rights to use the licensed patent rights and technology to improve the patent rights, carry out educational purposes, and for the development of the patent rights where BPS cannot obtain regulatory approval or meet demand. BPS may also grant sublicenses under the PHAC License, provided that each sublicense is consistent with the terms and conditions of the PHAC License and contain certain mandatory sublicensing provisions.

We granted a sublicense under the PHAC License to Merck in November 2014 when we entered into a license and collaboration agreement with Merck to develop and potentially commercialize our Ebola vaccine product candidate. The PHAC License provides express consent for Merck to sublicense or subcontract its sublicensed rights under certain circumstances.

In consideration of the license grants, under the terms of the PHAC License, BPS must pay to Canada annual license maintenance fees, patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $250,000, and royalties as a low single-digit percentage of the sales price of the licensed products sold by BPS, its affiliates or sublicensees in countries outside of Africa and GAVI eligible countries, which royalty rate varies depending on whether additional technology licenses are required to sell the licensed product, and whether the licensed product is covered by a valid claim of a patent licensed under the PHAC License. In addition to the milestones and royalties discussed above, BPS is required to pay to Canada a percentage in the low double digits of certain consideration BPS receives from Merck or any other sublicensee over specified thresholds. BPS is obligated to use commercially reasonable efforts to develop and market the licensed products. If BPS breaches its obligations and fails to cure the breach, PHAC may terminate the PHAC License.

In November 2014, we entered into a licenses and collaboration agreement with Merck to develop and potentially commercialize our Ebola vaccine product candidate. The Merck Agreement includes a sublicense of the patents subject to the PHAC License.

Unless terminated earlier, the PHAC License will remain in effect until the earlier of (i) July 28, 2033; or (ii) such time that BPS and its sublicensees cease all development and commercialization of the technologies that are licensed to the Company under the PHAC License. Canada may terminate this agreement for BPS's failure to use commercially reasonable efforts to commercialize, failure to pay, breach of confidentiality, cessation of business, criminal conviction or other breach of its obligations under the agreement. BPS may not assign the PHAC License to a third party without the prior written consent of Canada, not to be unreasonably withheld. This agreement will terminate automatically if BPS files for bankruptcy or similar proceedings or if BPS assigns the PHAC License under certain circumstances without prior written consent of Canada.

Government Regulation

We operate in a highly regulated industry that is subject to significant federal, state, local and foreign regulation. Our present and future business has been, and will continue to be, subject to a variety of laws including, the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, among others.

The FDCA and other federal and state statutes and regulations govern the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these laws and regulations, product development and product approval processes are very expensive and time consuming.

FDA Approval Process

In the United States, pharmaceutical products, including biologics, are subject to extensive regulation by the FDA. The FDCA and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, or NDAs, or BLAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug or biologic for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation as well as animal trials to assess the characteristics and potential pharmacology and toxicity of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not objected to the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, good clinical practices, or GCP, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The clinical trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions. Clinical trials to support NDAs or BLAs, which are applications for marketing approval, are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population, to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage, and identify common adverse effects and safety risks.

If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

In the case of product candidates for severe or life-threatening diseases such as cancer, the initial human testing is often conducted in patients rather than in healthy volunteers. Since these patients already have the target disease, these studies may provide initial evidence of efficacy traditionally obtained in Phase 2 clinical trials and thus these trials are frequently referred to as Phase 1b clinical trials. Additionally, when product candidates can damage normal cells, it is not ethical to administer such drugs to healthy patients in a Phase 1 clinical trial. After completion of the required clinical testing, an NDA or, in the case of a biologic, a BLA, is prepared and submitted to the FDA. FDA approval of the marketing application is required before marketing of the product may begin in the U.S. The

marketing application must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. Submission of an NDA or BLA also requires the payment of a substantial user fee, unless a waiver applies.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of marketing applications. Most such applications for non-priority drug products are reviewed within 10 months of their acceptance for filing, and for priority designated applications, within six months of their acceptance for filing. The review process may be extended by the FDA for three additional months to consider new information submitted during the review or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a marketing application, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. The FDA may also inspect one or more non-clinical study sites to assure compliance with GLP. Additionally, the FDA will inspect the proposed facility or the facilities at which the drug substance or drug product is manufactured, tested, packaged or labeled. The FDA will not approve the product unless it has compliance with GCP, GLP, and current good manufacturing practices, or cGMPs, and the marketing application (the NDA or, in the case of biologics, the BLA) contains data that provide substantial evidence that the drug is safe and effective in the indication or indications studied. Manufacturers of biologics also must comply with FDA's general biological product standards to demonstrate that the product is safe, pure and potent.

After the FDA evaluates the marketing application and the manufacturing facilities, it issues an Approval Letter, or a Complete Response letter. A Complete Response letter outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed in a resubmission of the marketing application, the FDA will re-initiate review. If it is satisfied that the deficiencies have been addressed, the FDA will issue an Approval Letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. It is not unusual for the FDA to issue a Complete Response letter because it believes that the drug is not safe enough or effective enough or because it does not believe that the data submitted are reliable or conclusive.

An Approval Letter authorizes commercial marketing of the drug with specific prescribing information for specific indication or indications. As a condition of approval of the marketing application, the FDA may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions and Risk Evaluation and Mitigation Strategies, or REMS, which can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The Hatch-Waxman Act

In seeking approval for marketing of a drug or biologic through an NDA or BLA, respectively, applicants are required to list with the FDA each patent with claims that cover the applicant's product or FDA approved method of using this product. Upon approval of a product, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not

been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA applicant and patent holders once the ANDA has been accepted for filing by the FDA. The NDA applicant and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification notification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active moiety, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which the FDA cannot grant effective approval of an ANDA based on that listed drug.

Ongoing Regulatory Requirements

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indication or indications and in accordance with the provisions of the approved labeling. However, physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications. Companies may also share truthful and not misleading information that is otherwise consistent with the labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement, or in the case of biologics, a new BLA or BLA supplement, before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA and BLA supplements as it does in reviewing NDAs and BLAs. We cannot be certain that the FDA or any other regulatory agency will grant approval for our product candidates for any other indications or any other product candidate for any indication on a timely basis, if at all.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies, and are subject to periodic unannounced, routine or for-cause inspections by the FDA during which the agency inspects manufacturing facilities to access compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It

is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

Federal and State Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to increase the transparency of and restrict certain marketing practices in the pharmaceutical and medical device industries in recent years. These laws include the Physician Payments Sunshine Act, anti-kickback statutes and false claims statutes.

Federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, are also applicable to our business. We could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. The laws that may affect our ability to operate include: the federal Anti-Kickback Statute, which prohibits soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters and was amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and the Physician Payments Sunshine Act, which requires certain pharmaceutical manufacturers to annually report information to CMS, as defined below, related to payments and other transfers of value to physicians, other healthcare providers and institutions, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members. There are also state law equivalents of each of the above federal laws, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Regulation Outside the United States

Drugs are also subject to extensive regulation outside of the United States. Whether or not we obtain approval in the United States, we will be subject to separate regulatory approval standards in foreign countries. In the E.U., for example, there is a centralized approval procedure that authorizes marketing of a product in all countries of the E.U. (which includes most major countries in Europe). If this procedure is not used, approval in one country of the E.U. can be used to obtain approval in another country of the E.U. under two simplified application processes, the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After regulatory approval is received through any of the European registration procedures, pricing and reimbursement approvals are also required in most countries.

Price Controls

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. In many of the markets where we may do business in the future, the prices of pharmaceutical products are subject to direct price controls (by law) and to reimbursement programs with varying price control mechanisms. In the United States, the Medicare program is administered by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. Coverage and reimbursement for products and services under Medicare are determined pursuant to regulations promulgated by CMS and pursuant to CMS’s subregulatory coverage and reimbursement determinations. It is difficult to predict how CMS may apply those regulations and subregulatory determinations to newly approved products, especially novel products, and those regulations and interpretive determinations are subject to change. Moreover, the methodology under which CMS makes coverage and reimbursement determinations is subject to change, particularly because of budgetary pressures facing the Medicare program. Medicare regulations and interpretive determinations also may determine who may be reimbursed for certain services.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged

for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider a drug product to be cost effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, risk sharing, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Such interest has resulted in several recent U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, on May 11, 2018, the President Trump laid out his administration's "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, will affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Although some of these and other proposals may require additional authorization to become effective, the U.S. congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. These controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals. As a result, the marketability of any product which receives regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement.

In addition, an increasing emphasis on managed care in the United States has increased and will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the ACA, contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. In the years since its enactment, there have been, and continue to be, significant developments in, and continued legislative activity around, attempts to repeal or repeal and replace the ACA. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by the U.S. congress as part of the Tax Cuts and Jobs Act of 2017, or the Tax Act. The Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision.

Due to these efforts, there is significant uncertainty regarding future of the ACA, and its impact on a pharmaceutical company's business and operations. Even if favorable coverage and reimbursement status is attained for one or more products that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the role of the National Institute for Health and Clinical Excellence in the United Kingdom, which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert commercial pressure on pricing within a country.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances and biological materials. We may incur significant costs to comply with such laws and regulations now or in the future.

Legal Proceedings

In addition to the legal proceedings described in Note 15 to the consolidated financial statements included in Item 8 of this Form 10-K, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Employees

As of December 31, 2018, we had 55 employees. None of our employees are subject to a collective bargaining agreement or represented by a labor or trade union, and we believe that our relations with our employees are good.

Facilities

Our executive offices and manufacturing facilities are located in the Iowa State University Research Park in Ames, Iowa. We have approximately 26,616 square feet, comprising executive office space and space dedicated to manufacturing, testing and product storage, leased with the Iowa State University Research Park Corporation. The leases expire March 31, 2021, and we have the option to extend the leases for two additional five-year periods upon the same terms as the base lease. We lease an additional 23,544 square feet in Ames, Iowa under a lease expiring on January 31, 2020.

We lease 2,686 square feet of additional executive and administrative space in Austin, Texas under a lease expiring in November 2019. We also entered into a lease for 3,255 square feet of additional clinical, regulatory and executive offices in Wayne, Pennsylvania beginning March 1, 2018 and expiring in February 2021.

Corporate Information

We were incorporated in the state of Delaware on June 4, 1999 under the name “NewLink Genetics Corporation.”

Available Information

We view our operations and measure our business as one reportable segment operating primarily in the United States. See Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information. Additional information required by this item is incorporated herein by reference to Part II, Item 6 “Selected Financial Data.”

Our website address is www.newlinkgenetics.com; however, information found on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K. We make available free of charge on or through our website copies of our Annual Report, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

You can read our SEC filings over the Internet at the SEC’s web site at *www.sec.gov*

Item 1A. RISK FACTORS

RISK FACTORS

Investing in our common stock involves significant risks, some of which are described below. In evaluating our business, investors should carefully consider the following risk factors. These risk factors contain, in addition to historical information, forward-looking statements that involve substantial risks and uncertainties. Our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below. The order in which the following risks are presented is not intended to reflect the magnitude of the risks described. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Business Risks

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them. We have not completed testing of any of our product candidates in controlled clinical trials.

The clinical development and regulatory approval process is expensive and time-consuming. The timing of any future product approval cannot be accurately predicted. If we fail to obtain regulatory approval for our current or future product candidates, we will be unable to market and sell them and therefore we may never be profitable.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required varies depending on the product candidate, the condition being evaluated, the trial results and regulations applicable to any particular product candidate. Any inability to successfully complete preclinical and clinical development could result in additional costs to us.

Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Initial results may not be confirmed upon full analysis of the detailed results of a trial. Product candidates in later-stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

We are heavily dependent on the success of the clinical development of indoximod, and if we fail to complete clinical trials, fail to demonstrate safety and efficacy in those clinical trials, fail to obtain regulatory approval or fail to successfully commercialize indoximod, our business, financial condition and results of operations would be harmed.

The indoximod clinical development program currently encompasses a number of Phase 1 and 2 combination trials across multiple cancer indications. If we fail to complete any of these trials or fail to obtain regulatory approval, our ability to commercialize indoximod will be materially and adversely affected and our business, financial condition and results of operations would be harmed.

If we make changes to any of our product candidates, additional clinical trials may be required resulting in additional costs and delays.

We have an ongoing research program to investigate potential opportunities to improve the potency, efficacy and/or safety profile of some of our product candidates through modifications to their formulations or chemical compositions. These efforts may not be successful. If a new formulation or composition appears promising, we may decide to undertake clinical development of such formulation or composition even if an existing product candidate has shown acceptable safety and efficacy in clinical trials. The nature and extent of additional clinical trials that might be required for a new formulation or composition would depend on many factors. If we were to decide to pursue clinical development of a new formulation or composition, we would incur additional costs and the timeline for

potential commercialization would be delayed. There can be no assurance that any new formulation or composition would prove to be safe or effective or superior to an existing product candidate. Any delay in commercialization of a new formulation or composition may adversely affect our competitive position.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle, including by allowing Investigational New Drug applications to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. Furthermore, our resource allocation decisions and our decisions about whether and how to develop or commercialize any particular product candidate may be based on evaluations of the scientific and commercial potential or target market for the product candidate that later prove to be materially inaccurate. If we enter into collaborations, licensing or other royalty arrangements to develop or commercialize a particular product candidate, we may relinquish valuable rights to that product candidate in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

We may face delays in completing our clinical trials, or we may not be able to complete them at all.

We have not completed all of the clinical trials necessary to support an application with the FDA for approval to market any of our product candidates. Our current and future clinical trials may be delayed or terminated as a result of many factors, including:

- we may experience delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- we may need to reformulate or change the dosing of our product candidates;
- our clinical trials may have slower than expected patient enrollment or lack of a sufficient number of patients that meet their enrollment criteria;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;
- we may experience difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our clinical trial protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials;
- our third-party contractors, including those manufacturing our product candidates or components of ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- we may experience governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines;

- enrollment in and conduct of our clinical trials may be adversely affected by the regulatory approval of competing agents in this class, competition with ongoing clinical trials or scheduling conflicts with participating clinicians; and
- we may experience delays in achieving clinical trial endpoints and completing data analysis for a trial.

In addition, we rely on academic institutions, physician practices and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other aspects of these clinical trials than if we conducted the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol or applicable regulations. We also may rely on clinical research organizations to perform our data management and analysis. They may not provide these services as required or in a timely or compliant manner.

Moreover, our development costs will increase if we are required to complete additional or larger clinical trials for our product candidates prior to FDA approval. If the delays or costs are significant, our financial results and ability to commercialize our product candidates will be adversely affected.

If we encounter difficulties enrolling patients in our clinical trials, our clinical trials could be delayed or otherwise adversely affected.

Clinical trials for our product candidates require us to identify and enroll a large number of patients with the disease under investigation, or healthy volunteers willing to participate in certain trials. We may not be able to enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a clinical trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- changes in the standard of care that make the trial as designed less attractive to clinicians and patients;
- availability of competing therapies and clinical trials, including announced clinical trials evaluating potentially competing IDO pathway inhibitors in clinical settings similar to our clinical trials;
- the results of clinical trials of other IDO pathway inhibitors;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Regulatory authorities may not approve our product candidates even if they meet safety and efficacy endpoints in clinical trials.

We have discussions with and obtain guidance from regulatory authorities regarding certain aspects of our clinical development activities. These discussions are not binding commitments on the part of regulatory authorities. Under certain circumstances, regulatory authorities may revise or retract previous guidance during the course of our clinical activities or after the completion of our clinical trials. A regulatory authority may also disqualify a clinical trial in whole or in part from consideration in support of approval of a potential product for commercial sale or otherwise deny approval of that product. Prior to regulatory approval, a regulatory authority may elect to obtain advice from outside experts regarding scientific issues and/or marketing applications under a regulatory authority review. In the United States, these outside experts are convened through the FDA's Advisory Committee process, which would

report to the FDA and make recommendations that may differ from the views of the FDA. The FDA is not bound by the recommendations of an Advisory Committee, but it typically follows such recommendations. In addition, should an Advisory Committee be convened, it would be expected to lengthen the time for obtaining regulatory approval, if such approval is obtained at all.

The FDA and other foreign regulatory agencies can delay, limit or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- our manufacturing processes or facilities may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional work on our part.

Any delay in, or failure to receive or maintain, approval for any of our product candidates could prevent us from ever generating meaningful revenues or achieving profitability in future years.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may change requirements for approval even after a clinical trial design has been approved. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

Under the Merck Agreement, we have ongoing obligations related to the development of our Ebola vaccine product candidate, which may result in greater costs and a longer timeframe for regulatory approval than we estimate, yet we will receive limited revenues, if any, from any future sales of our Ebola vaccine product candidate.

Under the Merck Agreement, we have ongoing obligations related to the development of our Ebola vaccine product candidate, including obligations related to clinical trials, government contracting and licensing of the vaccine technology, which may cause us to incur costs or losses materially larger than we expect. However, because we have exclusively licensed the right to research, develop, manufacture and distribute our Ebola vaccine product candidate to Merck and we are only entitled to certain royalty and other payments under the Merck Agreement, we will receive limited revenues, if any, even if we or Merck are successful in developing and commercializing our Ebola vaccine product candidate.

The time and cost of product development and the timeframe for regulatory approval of any Ebola vaccine product candidate are uncertain and may be longer and more costly than we estimate. Our Ebola vaccine product candidate is a live virus based on vesicular stomatitis virus, or VSV. There are no commercial vaccines based upon this virus, and unforeseen problems related to the use of our live virus vaccine may prevent or materially increase costs and delays of further development or approval of our Ebola vaccine product candidate. There may be unknown safety risks associated with the vaccine, and regulatory agencies such as the FDA may require us to conduct extensive safety testing prior to approval to demonstrate a low risk of rare and severe adverse events caused by the vaccine.

Public perception of vaccine safety issues, including adoption of novel vaccines based upon VSV, may adversely influence willingness of subjects to participate in clinical trials, or if approved, of physicians to prescribe, and of patients to receive, novel vaccines. For example, our Ebola vaccine product candidate is currently being developed for prevention of, and may later be developed for treatment of patients infected with, Ebola, and public aversion to vaccines for Ebola or vaccines in general may adversely influence later-stage clinical trials of this product candidate or, if approved, its commercial success.

Even if approved, a number of factors may adversely affect commercial sales. Lack of familiarity with the viral vaccine and potential adverse events associated with vaccination may adversely affect physician and patient perception and uptake of our potential product. Furthermore, there are no assurances that the vaccine will be approved for inclusion in government stockpile programs, which may be material to the commercial success of the product candidate, either in the United States or abroad. If our Ebola vaccine product candidate eventually is approved and sold commercially, we will receive limited revenues under the Merck Agreement. Finally, in certain cases, our obligations to pay royalties to PHAC may exceed the royalties we receive from Merck.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's Good Clinical Practice, or GCP, requirements, or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and Institutional Review Boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under current Good Manufacturing Practice, or cGMP, requirements and may require large numbers of test subjects. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- the product candidate may have unforeseen adverse side effects;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- failure to demonstrate a benefit from using a drug;
- the quality or stability of the product candidate may fall below acceptable standards; or
- insufficient quantities of the product candidate to complete the trials.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors indoximod, NLG802, NLG207, NLG919, and other product candidates could take significantly longer to gain regulatory approval than we expect or we may never gain approval for additional indications, which could reduce our revenue by delaying or terminating their commercialization.

Some of our product candidates have been studied, or in the future may be studied, in clinical trials co-sponsored by organizations or agencies other than us, or in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.

We supplied indoximod in support of a Phase 2 investigator-initiated clinical trial, and we provided clinical supply of dorgenmeltucel-L in support of a Phase 2 investigator-initiated clinical trial. Our Ebola vaccine product candidate was studied in clinical trials in West Africa. We may continue to supply and otherwise support similar trials in the future. However, because we are not the sponsors of these trials, we do not control the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment, and, as a result, are subject to risks associated with the way these types of trials are conducted, in particular should any problems arise. These risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data.

If we cannot demonstrate the safety of our product candidates in preclinical and/or other non-clinical studies, we will not be able to initiate or continue clinical trials or obtain approval for our product candidates.

In order to move a product candidate not yet being tested in humans into a clinical trial, we must first demonstrate in preclinical testing that the product candidate is safe. Furthermore, in order to obtain approval, we must also demonstrate safety in various preclinical and non-clinical tests. We may not have conducted or may not conduct in the future the types of preclinical and other non-clinical testing ultimately required by regulatory authorities, or future preclinical tests may indicate that our product candidates are not safe for use in humans. Preclinical testing is expensive, can take many years and can have an uncertain outcome. In addition, success in initial preclinical testing does not ensure that later preclinical testing will be successful. We may experience numerous unforeseen events during, or as a result of, the preclinical testing process, which could delay or prevent our ability to develop or commercialize our product candidates, including:

- our preclinical testing may produce inconclusive or negative safety results, which may require us to conduct additional preclinical testing or to abandon product candidates that we believed to be promising;

- our product candidates may have unfavorable pharmacology, toxicology or carcinogenicity;
- our product candidates may cause undesirable side effects; and
- the FDA or other regulatory authorities may determine that additional safety testing is required.

Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition and results of operations.

Even if ultimately approved, indoximod, NLG802, NLG207, NLG919, our Ebola vaccine product candidate or any other potential product we or our collaborators may commercialize and market may be later withdrawn from the market or subject to promotional limitations.

We or our collaborators may not be able to obtain the labeling claims necessary or desirable for the promotion of any potential future products. We or our collaborators may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory, the FDA or a comparable agency in a foreign country may withdraw marketing authorization or may condition continued marketing on commitments from us or our collaborators that may be expensive and/or time consuming to fulfill. In addition, if we or others identify adverse side effects after any of our potential products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our potential products, additional clinical trials, changes in labeling of our potential products and/or additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of our potential products.

We will need to develop or acquire additional capabilities in order to commercialize any product candidates that obtain FDA approval, and we may encounter unexpected costs or difficulties in doing so.

We will need to acquire additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. Currently, we have limited experience in preparing applications for marketing approval, commercial-scale manufacturing, managing large-scale information technology systems or managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources.

To do this effectively, we must:

- train, manage and motivate a growing employee base;
- accurately forecast demand for our products; and
- expand existing operational, financial and management information systems.

We will need to increase our manufacturing capacity, which may include negotiating and entering into additional third-party agreements to meet our commercial manufacturing requirements.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate significant product revenue.

We do not have a sales organization and have no experience in the sales and distribution of pharmaceutical products. There are risks involved with establishing our own sales capabilities and increasing our marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us could potentially be lower than if we market and sell these products ourselves.

We entered into the Merck Agreement in November 2014 for the research, development, manufacture and distribution of our Ebola vaccine product candidate. Even if our Ebola vaccine product candidate is approved by regulators for marketing and sale, Merck may be unsuccessful in its efforts to commercialize our Ebola vaccine product candidate, respectively, or may devote fewer resources to such efforts than we would consider optimal.

We may establish our own specialty sales force and/or engage other biopharmaceutical or other healthcare companies with established sales, marketing and distribution capabilities to sell, market and distribute any future products. We may not be able to establish a specialty sales force or establish sales, marketing or distribution relationships on acceptable terms. Factors that may inhibit our efforts to commercialize any future products without strategic collaborators or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to an adequate number of physicians to educate them about the attributes of any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Because the establishment of sales, marketing and distribution capabilities depends on the progress toward commercialization of our product candidates, and because of the numerous risks and uncertainties involved with establishing those capabilities, we are unable to predict when, if ever, we will establish our own sales, marketing and distribution capabilities. If we are not able to collaborate with third parties and are unsuccessful in recruiting sales, marketing and distribution personnel or in building the necessary infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

Failure to attract and retain key personnel could impede our ability to develop our products and to obtain new collaborations or other sources of funding.

Because of the specialized scientific nature of our business, our success is highly dependent upon our ability to attract and retain qualified scientific and technical personnel, consultants and advisors. We are highly dependent on the principal members of our scientific and management staff. The long-term loss of services of key executives might significantly delay or prevent the achievement of our research, development, and business objectives. We do not maintain key-man life insurance with respect to any of our employees, nor do we intend to secure such insurance.

We will need to recruit additional personnel in order to achieve our operating goals. In order to pursue product development and marketing and sales activities, if any, we will need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales. We also rely on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on acceptable terms, if at all. Additionally, our most significant facility is located in Iowa, which may make attracting and retaining qualified scientific and technical personnel from outside of Iowa difficult. The failure to attract and retain qualified personnel, consultants and advisors could have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to Manufacturing Activities

We rely on third-party manufacturers to produce our preclinical and clinical product candidate supplies and we intend to rely on third parties to produce commercial supplies of any product candidates that may be approved in the future. Any failure by a third-party manufacturer to produce supplies for us may delay or impair our ability to complete our clinical trials or commercialize our product candidates.

We do not possess all of the capabilities to fully commercialize any of our product candidates on our own. If we are unable to arrange for third-party manufacturing sources, or to do so on commercially reasonable terms, we may not be able to complete development of such product candidates or market them. In addition, we currently rely on our partner Merck for the supply of our Ebola vaccine product candidate and other third-party manufacturers for our supply of indoximod, NLG802, NLG207, and NLG919 for preclinical and clinical studies. Problems with any of our facilities or processes, or our contract manufacturers' facilities or processes, could prevent or delay the production of adequate supplies of indoximod, NLG802, NLG207, NLG919, our Ebola vaccine product candidate or other finished products.

Any prolonged delay or interruption in the operations of our current or future contract manufacturers' facilities could result in cancellation of shipments, loss of components in the process of being manufactured or a shortfall in

availability of a product. A number of factors could cause interruptions, including the inability of a supplier to provide raw materials, equipment malfunctions or failures, damage to a facility due to natural disasters, changes in international or U.S. regulatory requirements or standards that require modifications to our manufacturing processes, action by regulatory authorities or by us that results in the halting or slowdown of production of components or finished product due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified production capacity and sufficiently trained or qualified personnel may not be available on a timely or cost-effective basis or at all. Difficulties or delays in our contract manufacturers' production of product candidates could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue and market share if we are unable to meet market demand for any products that are approved for sale on a timely basis.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, failure of the third party to accept orders for supply of drug substance or drug product and the possibility of termination or nonrenewal of the agreement by the third party based on its own business priorities and at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes as needed, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates that may have been granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture our product candidates. Such suppliers may not sell this capital equipment or these raw materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of this capital equipment or these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Because of the complex nature of many of our early stage compounds and product candidates, our manufacturers may not be able to manufacture such compounds and product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize related products. If we successfully commercialize any of our product candidates, we may be required to establish or access large-scale commercial manufacturing capabilities. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. To meet our projected needs for commercial manufacturing in the event that one or more of our product candidates gains marketing approval, third parties with whom we currently work will need to increase their scale of production or we will need to secure alternate suppliers.

Furthermore, we do not currently have experience with the management of relationships related to commercial-scale contract manufacturing, and we may incur substantial costs to develop the capability to negotiate and enter into relationships with third-party contract manufacturers.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our products.

All entities involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our Company, our existing contract manufacturers and those we may engage in the future, and Merck in its capacity as our licensee, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP regulations. These regulations govern manufacturing processes and procedures (including record keeping) and the

implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of any of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. In addition, to the extent that we rely on foreign contract manufacturers, as we do currently for our Ebola vaccine product candidate, we are or will be subject to additional risks including the need to comply with export and import regulations.

If our current or future contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

Our facility is located in areas where floods and tornados are known to occur, and the occurrence of a flood, tornado or other catastrophic disaster could damage our facilities and equipment, which could cause us to curtail or cease operations.

Our primary facility is located in Ames, Iowa, which is susceptible to floods and tornados, and our facility is therefore vulnerable to damage or disruption from floods and tornados. We are also vulnerable to damage from other types of disasters, such as power loss, fire and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We currently carry business insurance (real, personal and business income) of nearly $11.6 million in the aggregate, but this policy does not cover disasters such as floods and earthquakes. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our information technology infrastructure, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber-attacks. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent the adverse effect of such events. Significant disruptions of our information technology systems or breaches of data security could adversely affect our business.

Risks Relating to Regulation of Our Industry

The industry within which we operate and our business are subject to extensive regulation, which is costly and time consuming and which may subject us to unanticipated delays.

The research, development, testing, manufacturing, labeling, packaging, marketing, distribution, promotion and advertising of biologic and pharmaceutical products such as our product candidates are subject to extensive regulation by governmental regulatory authorities in the United States and other countries. The drug development and approval process is generally lengthy, expensive and subject to unanticipated delays. Data obtained from preclinical and

clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of development and regulatory review of each submitted application for approval. To obtain approval for a product candidate, we must demonstrate to the satisfaction of the regulatory authorities that the product candidate is safe and effective in the case of a small-molecule pharmaceutical product, or is safe, pure and potent in the case of a biologic, which typically takes several years or more depending upon the type, complexity and novelty of the product and requires the expenditure of substantial resources.

There can be no assurance that we will not encounter problems in clinical trials that would cause us or the regulatory authorities to delay or suspend clinical trials. Any such delay or suspension could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that we will not encounter problems in clinical trials that would cause us or the regulatory authorities to delay or suspend clinical trials. Any such delay or suspension could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that clinical trials for any of our product candidates currently under development will be completed successfully or within any specified time period, if at all. Further, there can also be no assurance that such testing will show any product to be safe, pure, potent or effective. We cannot predict when, if ever, we might submit for regulatory review our product candidates currently under development. In addition, regardless of how much time and resources we devote to development of a product candidate, there can be no assurance that regulatory approval will be obtained for that product candidate.

Even if such regulatory approval is obtained, we, our products and any contract manufacturers or commercial collaborators of ours will be subject to continual regulatory review in both the United States and other countries. Later discovery of previously unknown problems with regard to a product, distributor or manufacturer may result in restrictions, including withdrawal of the product from the market and/or disqualification or decertification of the distributor or manufacturer. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- warning letters;
- civil or criminal penalties;
- injunctions;
- suspension of or withdrawal of regulatory approval;
- total or partial suspension of any ongoing clinical trials or of production;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of new biologic and pharmaceutical products through lengthy and detailed preclinical and clinical testing procedures, sampling activities and other costly and time-consuming compliance procedures. Clinical trials are vigorously regulated and must meet requirements for FDA review and oversight and requirements under GCP guidelines. A new drug may not be marketed in the United States until the FDA has approved it. There can be no assurance that we will not encounter delays or rejections or that the FDA will not make policy changes during the period of product development and FDA regulatory review of each submitted BLA and NDA. A delay in obtaining, or failure to obtain, such approvals would have a material adverse effect on our business, financial condition and results of operations. Even if regulatory approval were obtained, it would be limited as to the indicated uses for which the product may be promoted or marketed. A marketed product, its manufacturer and the facilities in which it is manufactured are subject to continual review and periodic inspections. If marketing approval is granted, we would be required to comply with FDA requirements for manufacturing, labeling, advertising, record-keeping and reporting of adverse experiences and other information. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label, although physicians, in the practice of medicine, may prescribe approved drugs

for unapproved indications. Companies may also share truthful and not misleading information that is otherwise consistent with the labeling. In addition, we would be required to continue to comply with federal and state anti-kickback and other healthcare fraud and abuse laws that pertain to the marketing of pharmaceuticals, among other things. Failure to comply with regulatory requirements and other factors could subject us to regulatory or judicial enforcement actions, including product recalls or seizures, injunctions, withdrawal of the product from the market, civil penalties, criminal prosecution, refusals to approve new products and withdrawals of existing approvals, as well as enhanced product liability exposure, any of which could have a material adverse effect on our business, financial condition and results of operations. Sales of our products outside the United States will be subject to foreign regulatory requirements governing clinical trials, marketing approval, manufacturing and pricing. Noncompliance with these requirements could result in enforcement actions or penalties or could delay introduction of our products in certain countries.

The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement outside the United States vary greatly from country to country. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Foreign regulatory authorities could also require additional testing. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our products and may have a material adverse effect on our results of operations and financial condition.

We are also subject to laws generally applicable to businesses including, but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistleblowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistleblowing claim, even if without merit, could result in costly litigation or regulatory action or otherwise harm our business, results of operations, financial condition, cash flow and future prospects.

The availability of coverage and amount of reimbursement for our product candidates, if approved, and the manner in which government and private payers may reimburse for our potential products, are uncertain.

In both the United States and foreign markets, sales of our proposed products will depend in part on the availability of coverage and reimbursement from third-party payers such as government health administration authorities, private health insurers and other organizations. In addition, the process for determining whether a third-party payor will provide coverage for a pharmaceutical typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payer will pay for the product once coverage is approved. Third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. There can be no assurance that our proposed products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Our future levels of revenues and profitability may be affected by the continuing efforts of governmental and third-party payers to contain or reduce the costs of healthcare. We cannot predict the effect that private sector or governmental health care reforms may have on our business, and there can be no assurance that any such reforms will not have a material adverse effect on our business, financial condition and results of operations. Legislation and regulations affecting the pricing of pharmaceuticals may change before any of our proposed products are approved for marketing. Adoption of such legislation could further limit reimbursement for medical products and services. As a result, we may elect not to market future products in certain markets.

Moreover, while we are in clinical trials, we will not be reimbursed for any of our materials used during the clinical trials, however, certain services rendered to clinical trial participants may be reimbursable by third-party payors for standard of care treatment if not otherwise reimbursed under the applicable clinical trial study budget.

The biopharmaceutical industry is subject to significant regulation and oversight in the United States, in addition to approval of products for sale and marketing; our failure to comply with these laws could harm our results of operations and financial condition.

In addition to FDA restrictions on marketing of biopharmaceutical products, our operations may be directly, or indirectly through our relationships with healthcare providers, customers and third-party payers, subject to various

federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute. These laws may impact, among other things, our proposed sales, and education programs, and these laws have been applied to restrict certain marketing practices in the biopharmaceutical industry. In addition, we may be subject to patient privacy regulation by both the U.S. federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, among others, the following:

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.
- The federal civil False Claims Act prohibits any person or entity from knowingly presenting, or causing to be presented, to the federal government a claim for payment or approval that is false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Several pharmaceutical and other health-care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of off-label promotion. Private parties may initiate qui tam whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit.
- The federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization on covered entities, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information.
- The FDCA prohibits, among other things, the adulteration or misbranding of drugs and medical devices.
- The federal Physician Payments Sunshine Act, and its implementing regulations require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members.
- Analogous state laws and regulations include: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers; state laws that require pharmaceutical companies to comply with the

pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information and that require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. It is possible that some of our business activities could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business, financial condition and results of operations.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that required that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order included a budget neutrality provision that required the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations that can be repealed to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. Further, on February 24, 2017, President Trump issued an Executive Order requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification. It is difficult to predict how these requirements will continue to be enforced, the extent to which they will continue to impact the FDA's ability to exercise its regulatory authority, and the negative impact they may have on our business.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The U.S. and some foreign jurisdictions are considering or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, in the United States, the pharmaceutical industry has been affected by the passage of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, which, among other things, imposed new fees on entities that manufacture or import certain branded prescription drugs and expanded pharmaceutical manufacturer obligations to provide discounts and rebates to certain government programs. There have been judicial and congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills

affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017, or the Tax Act. The Texas U.S. District Court Judge, as well as the presidential administration and the Centers for Medicare and Medicaid Services, or CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

In addition, there has been particular and increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices in recent years, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. There have been several recent U.S. Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2018, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the "Wholesale Acquisition Cost", or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to U.S. federal healthcare Anti-Kickback Statute safe harbors which, among other things, will affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Although some of these and other proposals may require authorization through additional legislation to become effective, Congress and the presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Any of these initiatives could harm our ability to generate revenues.

In the future, there will likely continue to be proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of drug products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Individual states are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payers or other restrictions could harm our business, results of operations, financial condition and

prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which pharmaceutical products and suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last 10 years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 ("Right to Try Act") was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislative or administrative action, either in the United States or abroad.

We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

Our research and development involves the controlled use of hazardous materials, chemicals, various active microorganisms and volatile organic compounds, and we may incur significant costs as a result of the need to comply with numerous laws and regulations. We are subject to laws and regulations enforced by the FDA, the Drug Enforcement Agency, foreign health authorities and other regulatory requirements, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Food, Drug and Cosmetic Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of our products, materials used to develop and manufacture our product candidates, and resulting waste products. Although we believe that our safety procedures for handling and disposing of such materials, and for killing any unused microorganisms before disposing of them, comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Failure to comply with existing or future data protection laws and regulations related to privacy or data security could lead to government enforcement actions (which could include civil or criminal fines or penalties), private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

Regulation of data processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. We and our partners may be subject to current, new, or modified federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our partners to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our partners' ability to process or use data in order to support the provision of our products or services, or affect our or our partners' ability to offer our products and services in certain locations.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal

Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to civil and/or criminal penalties including if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including, without limitation, the European Union Directive 95/46/EC, or the Directive, and the European Union's General Data Protection Regulation, or the GDPR, that took effect in May 2018, and member state data protection legislation, may also apply to health-related and other personal information obtained outside of the United States. These laws impose strict obligations on the ability to process health-related and other personal information of data subjects in the European Union, including in relation to use, collection, analysis and transfer of such personal information. These laws include several requirements relating to the consent of the individuals to whom the personal data relates, limitations on data processing, establishing a legal basis for processing, notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, the security and confidentiality of the personal data and various rights that data subjects may exercise.

The Directive and the GDPR prohibits, without an appropriate legal basis, the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions.

Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with European Union data protection laws remains. For example, ongoing legal challenges in Europe to the mechanisms allowing companies to transfer personal data from the EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers, such as the European Union-U.S. and Swiss-U.S. Privacy Shield framework. Additionally, other countries have passed or are considering passing laws requiring local data residency.

Under the GDPR, regulators may impose substantial fines and penalties for non-compliance. Companies that violate the GDPR can face fines of up to the greater of 20 million Euros or 4% of their worldwide annual turnover (revenue). The GDPR has increased our responsibility and liability in relation to personal data that we process, requiring us to put in place additional mechanisms to ensure compliance with the GDPR and other EU and international data protection rules.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations related to security or privacy, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Compliance with data protection laws may be time-consuming, require additional resources and could result in increased expenses, reduce overall demand for our products and services and make it more difficult to meet expectations of or commitments to customers or partners.

Any of these matters could materially adversely affect our business, financial condition, or operational results.

Financial Risks

We have a history of net losses. We incurred a net loss for the years ended December 31, 2016, 2017 and 2018 and expect to continue to incur net losses for the foreseeable future, and we may never achieve or maintain profitability in the future.

We were profitable in the year ended December 31, 2014, primarily as a result of upfront payments under the Genentech Agreement and the Merck Agreement. We are not entitled to receive any additional upfront payments under these licensing or collaboration agreements. We do not expect any milestone or royalty payments under these

or other agreements, if any, to be sufficient to make us profitable in future years. We incurred a loss of $53.6 million for the year ending December 31, 2018 and we do not expect to be profitable for the foreseeable future. We anticipate that we will continue to incur operating losses over the next several years as we continue our clinical development programs.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities, government grants, economic development loans and capital lease and equipment financing. The size of our future net losses will depend, in part, on the rate of growth or contraction of our expenses and the level and rate of growth, if any, of our revenues. Our ability to achieve profitability in future years is dependent on our ability, alone or with others, to complete the development of our products successfully, obtain the required regulatory approvals, manufacture and market our proposed products successfully or have such products manufactured and marketed by others and gain market acceptance for such products. There can be no assurance as to whether or when we will achieve profitability.

We may require substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

Development of our product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution capabilities, either internally or through collaborations with third parties. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings (including FDA review of any BLA or NDA we file);
- payments required with respect to development milestones we achieve under our in-licensing agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the costs associated with commercializing our product candidates, if they receive regulatory approval;
- the cost of manufacturing our product candidates and any products we commercialize;
- the cost and timing of developing our ability to establish sales and marketing capabilities;
- the potential requirement to repay our outstanding government provided loans;
- competing technological efforts and market developments;
- changes in our existing research relationships;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing and receipt of revenues from existing or future products, if any; and
- payments received under any future strategic collaborations.

We anticipate that we will continue to generate significant losses in the future as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates. We believe that our existing cash and cash equivalents will allow us to fund our operating plan in the near and medium term. However, our operating plan may change as a result of factors currently unknown to us.

There can be no assurance that our revenue and expense forecasts will prove to be accurate, and any change in the foregoing assumptions could require us to obtain additional financing earlier than anticipated. There is a risk of delay

or failure at any stage of developing a product candidate, and the time required and costs involved in successfully accomplishing our objectives cannot be accurately predicted. Actual drug research and development costs could substantially exceed budgeted amounts, which could force us to delay, reduce the scope of or eliminate one or more of our research or development programs.

We are party to license agreements with various parties pursuant to which we have obtained licenses to certain patents, patent applications and other intellectual property related to our product candidates and product development efforts. We are obligated to make aggregate payments ranging from approximately $250,000 to $2.8 million under our license agreements (and in some cases, for each product candidate in such license) upon achievement of development and regulatory approval milestones specified in the applicable license. The timing of our achievement of these events and corresponding milestone payments to our licensors is subject to factors relating to the clinical and regulatory development and commercialization of our product candidates, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization or marketing efforts or seek funds to meet these obligations on terms unfavorable to us.

We may never be able to generate a sufficient amount of product revenue to cover our expenses. Until we do, we expect to seek additional funding through public or private equity or debt financings, collaborative relationships, capital lease transactions or other available financing transactions. However, there can be no assurance that additional financing will be available on acceptable terms, if at all, and such financings could be dilutive to existing stockholders. Moreover, in the event that additional funds are obtained through arrangements with collaborators, such arrangements may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs. Our failure to obtain adequate financing when needed and on acceptable terms would have a material adverse effect on our business, financial condition and results of operations.

Even though we have received governmental support in the past, we may not continue to receive support at the same level or at all.

We have received significant financial assistance, primarily in the form of forgivable loans, from state and local governments. We have also received significant financial assistance, primarily in the form of grants and contracts, from federal agencies to support our infectious disease research. There can be no assurance that we will continue to receive the same level of assistance from these or other government agencies, if at all.

Through our subsidiary, BioProtection Systems Corporation, or BPS, we have received funding from multiple government agencies for our Ebola vaccine product candidate development efforts. There is no guarantee that we will receive sufficient, or any, future grant funding to meet our obligations related to our Ebola vaccine development or that we or Merck will succeed in developing an Ebola vaccine. The termination of a United States government grant, contract or relationship as a result of our failure to satisfy any of our obligations under the grants or contracts would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, there can be no assurance that we will secure comparable contracts with, or grants from, the United States government in the future.

Changes in our effective income tax rate could adversely affect our results of operations in the future.

For the twelve months ended December 31, 2018, we recorded a $7.0 million tax benefit. Our effective income tax rate, as well as our relative domestic and international tax liabilities, will depend in part on the allocation of any future income among different jurisdictions. In addition, various factors may have favorable or unfavorable effects on our effective income tax rate in individual jurisdictions or in the aggregate. These factors include whether tax authorities agree with our interpretations of existing tax laws, any required accounting for stock options and other share-based compensation, changes in tax laws and rates (including the recently enacted U.S. federal income tax law changes), our future levels of research and development spending, changes in accounting standards, changes in the mix of any future earnings in the various tax jurisdictions in which we may operate, the outcome of any examinations by the U.S. Internal Revenue Service or other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings. The effect on our income tax liabilities resulting from the above-mentioned factors or other factors could have a material adverse effect on our results of operations.

The recently enacted comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017 the Tax Act was signed into law. The Tax Act significantly revised the Internal Revenue Code of 1986, as amended, or the Code,and included, among other things, significant changes to corporate taxation, including a reduction of the corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income for net operating losses arising in taxable years beginning after December 31, 2017 and elimination of net operating loss carrybacks for net operating losses arising in taxable years beginning after December 31, 2017, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to the Tax Act and the potential tax consequences of investing in or holding our common stock.

Risks Relating to Competition

We compete in an industry characterized by extensive research and development efforts and rapid technological progress. New discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive.

New developments occur and are expected to continue to occur at a rapid pace, and there can be no assurance that discoveries or commercial developments by our competitors will not render some or all of our potential products obsolete or non-competitive, which would have a material adverse effect on our business, financial condition and results of operations.

We expect to compete with fully integrated and well-established pharmaceutical and biotechnology companies in the near and long term. Most of these companies have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. Such companies may succeed in discovering and developing pharmaceutical products more rapidly than we do or pharmaceutical products that are safer, more effective or less costly than any that we may develop. Such companies also may be more successful than we are in production and marketing. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations also conduct clinical trials, seek patent protection and establish collaborative arrangements for the development of oncology products.

We may face competition based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, reimbursement coverage, price and patent position. There can be no assurance that our competitors will not develop safer and more effective products, commercialize products earlier than we do, or obtain patent protection or intellectual property rights that limit our ability to commercialize our products.

There can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide us with proprietary protection or a competitive advantage.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Many of the products that we are attempting to develop and commercialize will be competing with existing therapies. In addition, a number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies both in the United States and abroad. Our competitors may utilize discovery technologies and techniques or collaborate with third parties in order to develop products more rapidly or successfully than we or our collaborators are able to do. Many of our competitors, particularly large pharmaceutical companies, have

substantially greater financial, technical and human resources than we do. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors.

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies, firms specialized in the development and production of vaccines, checkpoint inhibitors, and other immunotherapies, and major universities and research institutions. Many companies have entered into the field of immuno-oncology and are developing or commercializing products in areas that we have targeted for product development. Some of these products use therapeutic approaches that may compete directly with our product candidates. Most of our competitors possess substantially greater financial, technical and human resources than we possess. In addition, many of our competitors have significantly greater experience than we have in conducting preclinical and nonclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of drugs and manufacturing facilities. Accordingly, our competitors may succeed in obtaining regulatory approval for drugs more rapidly than we do. We expect to face growing competition for enrollment of patients in our clinical trials, which could delay or adversely affect our ability to complete such trials. We may also be adversely affected by the clinical trial results of our competitors. For example, if a competitor announces inconclusive or negative clinical trial results with respect to an IDO pathway inhibitor, expectations about IDO pathway inhibitors may be generally impacted and we may experience difficulty in enrolling patients in our indoximod trials. If we obtain regulatory approval and launch commercial sales of our product candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

We also face competition from pharmaceutical and biotechnology companies, academic institutions, government agencies and private research organizations in recruiting and retaining highly qualified scientific personnel and consultants and in the development and acquisition of technologies. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, thereby preventing us from obtaining technology on commercially reasonable terms, if at all. We will also compete for the services of third parties that may have already developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies to target the diseases on which we have focused both inside and outside of the United States.

Our competitive position will also depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often lengthy period between technological conception and commercial sales. We will require substantial capital resources to complete development of some or all of our products, obtain the necessary regulatory approvals and successfully manufacture and market our products. In order to secure capital resources, we may elect to sell additional capital stock, which would dilute the holdings of existing stockholders. We may also attempt to obtain funds through research grants and agreements with commercial collaborators. However, these types of financings are uncertain because they are at the discretion of the organizations and companies that control the funds. Accordingly, we may not receive any additional funds from grants or collaborations.

Research and discoveries by others may result in breakthroughs that render indoximod, NLG802, NLG207, and NLG919 product candidates, or our other potential products obsolete even before they begin to generate any revenue. If the FDA approves the commercial sale of any of our product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited or no experience. We expect that competition among products approved for sale will be based, among other things, on product efficacy, price, safety, reliability, availability, patent protection, and sales, marketing and distribution capabilities. Our profitability and financial position will suffer if our products receive regulatory approval but cannot compete effectively in the marketplace.

Our future products, if any, may not be accepted in the marketplace and therefore, we may not be able to generate significant revenue, or any revenue.

Even if our potential products are approved for sale, physicians and the medical community may not ultimately use them or may use them only in applications more restricted than we expect. Our future products, if successfully developed, will compete with a number of traditional immuno-oncology products manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products will also compete with new products currently under development by such companies and others. Physicians will prescribe a product only if they

determine, based on experience, clinical data, side effect profiles and other factors, that it is beneficial as compared to other products currently in use. Many other factors influence the adoption of new products, including marketing and distribution restrictions, course of treatment, adverse publicity, product pricing, the views of thought leaders in the medical community and coverage and adequate reimbursement by government and private third-party payers.

Risks Relating to Our Arrangements with Third Parties

We rely on third parties to conduct our preclinical studies and our clinical trials. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for our product candidates, or we may be delayed in doing so.

We do not have the ability to conduct preclinical studies or clinical trials independently for our product candidates. We must rely on third parties, such as contract research organizations, medical institutions, academic institutions, clinical investigators and contract laboratories, as well as our strategic collaborators and the third parties that they may use, to conduct our preclinical studies and clinical trials. Other than to the extent that Merck is responsible for clinical trials of our Ebola vaccine product candidate, we are responsible for confirming that our studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with GLP for conducting and recording the results of our preclinical studies and with GCP for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with GCP, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be more costly than expected or budgeted, be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or to commercialize the product candidate being tested in such trials, or may be delayed in doing so.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

We are also dependent on Merck for the development of the product candidates that are the subject of the Merck Agreement. If the company does not succeed in advancing the product candidate to final approval, or decides to discontinue its collaboration with us, such failure or decision, could materially harm our business.

If we fail to enter into any needed collaboration agreements for our product candidates, or if we enter into collaborations that are ultimately unsuccessful, we may be unable to commercialize any potential product effectively or at all.

To successfully commercialize any potential product, we will need substantial financial resources as well as expertise and physical resources and systems. We may elect to develop some or all of these physical resources and systems and expertise ourselves or we may seek to collaborate with another company that can provide some or all of such physical resources and systems as well as financial resources and expertise, as we did in the case of the Genentech Agreement and the Merck Agreement. Such collaborations are complex, and any potential discussions may not result in a definitive agreement for many reasons. For example, whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator’s evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the potential market for the subject product candidates, the costs and complexities of manufacturing and delivering the potential product to patients, the potential of competing products, the existence of uncertainty with respect to ownership or the coverage of our technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. If we were to determine that a collaboration for a potential product is necessary or beneficial and were unable to enter into such a collaboration on acceptable terms, we might elect to delay or scale back the commercialization of the potential product in order to preserve our financial resources or to allow us adequate time to develop the required physical resources and systems and expertise ourselves.

If we enter into a collaboration agreement we consider acceptable, including the Merck Agreement to develop and commercialize our Ebola vaccine product candidate, the collaboration may not proceed as quickly, smoothly or successfully as we plan. The risks in a collaboration agreement include the following:

- the collaborator may not apply the expected financial resources, efforts or required expertise in developing the physical resources and systems necessary to successfully commercialize the subject potential product;
- the collaborator may not invest in the development of a sales and marketing force and the related infrastructure at levels that ensure that sales of the potential product reach their full potential;
- disputes may arise between us and a collaborator that delay the commercialization or adversely affect its sales or profitability of the potential product; or
- the collaborator may independently develop, or develop with third parties, products that could compete with the potential product.

Under the Merck Agreement and any other collaboration for our product candidates, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates, and such disputes may be difficult and costly to resolve or may not be resolved. In addition, a collaborator for the potential product may have the right to terminate the collaboration at its discretion, or to discontinue development of a particular product candidate. For example, in June 2017, Genentech gave notice that it was terminating the Genentech Agreement with respect to NLG919 and gave notice in May 2018 that the remainder of the Agreement would terminate no later than November 6, 2018. Further, Merck has the right to terminate the Merck Agreement for any reason after a specified advance notice period. Any termination may require us to seek a new collaborator, which we may not be able to do on a timely basis, if at all, or may require us to delay or scale back the development or commercialization efforts. The occurrence of any of these events could adversely affect the development or commercialization of the potential product and materially harm our business and stock price by delaying the sale of any product that may be approved by the FDA in the future, by slowing the growth of such sales, by reducing the profitability of the product and/or by adversely affecting the reputation of the product.

We may explore strategic collaborations that may never materialize or may fail.

We may, in the future, periodically explore a variety of possible strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in the process of seeking appropriate strategic collaborators, and such collaborations can be complicated and time consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

We are required under the Merck Agreement, and we may be required under other collaborations, to relinquish important rights to and control over the development of our product candidates to our collaborators or otherwise be subject to unfavorable terms.

Our collaborations, including any future strategic collaborations we enter into, could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- other than under the Merck Agreement, we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;

- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may also adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Risks Relating to Protecting Our Intellectual Property

If we are unable to protect our proprietary rights or to defend against infringement claims, we may not be able to compete effectively or operate profitably.

Our success will depend, in part, on our ability to obtain patents, operate without infringing the proprietary rights of others and maintain trade secrets, both in the United States and other countries. Patent matters in the biotechnology and pharmaceutical industries can be highly uncertain and involve complex legal and factual questions. Accordingly, the validity, breadth, and enforceability of our patents and the existence of potentially blocking patent rights of others cannot be predicted, either in the United States or in other countries.

There can be no assurance that we will discover or develop patentable products or processes, or that patents will issue from any of the currently pending patent applications or that claims granted on issued patents will be sufficient to protect our technology or adequately cover the products we may actually sell. Potential competitors or other researchers in the field may have filed patent applications, been issued patents, published articles or otherwise created prior art that could restrict or block our efforts to obtain additional patents. There also can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated, rendered unenforceable or circumvented or that the rights granted thereunder will provide us with proprietary protection or competitive advantages. Our patent rights also depend on our compliance with technology and patent licenses upon which our patent rights are based and upon the validity of assignments of patent rights from consultants and other inventors that were, or are, not employed by us.

In addition, competitors may manufacture and sell our potential products in those foreign countries where we have not filed for patent protection or where patent protection may be unavailable, not obtainable or ultimately not enforceable. In addition, even where patent protection is obtained, third-party competitors may challenge our patent claims in the various patent offices, for example via opposition in the European Patent Office or reexamination or interference proceedings in the United States Patent and Trademark Office, or USPTO. The ability of such competitors to sell such products in the United States or in foreign countries where we have obtained patents is usually governed by the patent laws of the countries in which the product is sold.

Merck, which has sublicensed our Ebola vaccine product candidate, has received correspondence from Yale University asserting that it owns certain intellectual property rights with respect to the Ebola vaccine that they assert,

among other things, may need to be licensed by Merck. We also received correspondence from Yale University relating to the research and construction of the Ebola vaccine product by our licensor PHAC. If Merck were required to pay royalties to Yale University, that could result in a reduction of Merck's royalty obligations to us. If Merck otherwise suffered damages as a result of claims by Yale University, it is possible that Merck could seek indemnification from us.

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair our ability to access additional capital and/or cost us significant funds to defend.

We intend to rely on patent rights for our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets.

We rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain regulatory exclusivity and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technologies and product candidates.

We have sought to protect our proprietary position by filing patent applications related to our technologies and product candidates that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable, or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection or data exclusivity, for our product candidates, we may not be able to compete effectively, and our business and results of operations would be harmed.

We may not have sufficient patent term protections for our product candidates to effectively protect our business.

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Additional patent terms may be available through a patent term adjustment process, resulting from the USPTO delays during prosecution. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from generic medications.

Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data exclusivity terms of our product candidates. We

will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our product candidates for an extended period after regulatory approval, if any, which would negatively impact our business, financial condition, results of operations, and prospects. If we do not have sufficient patent terms or regulatory exclusivity to protect our product candidates, our business and results of operations will be adversely affected.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office has developed regulations and procedures to govern administration of the Leahy-Smith Act, but many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first-inventor-to-file provisions, only became effective 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We may be subject to litigation with respect to the ownership and use of intellectual property that will be costly to defend or pursue and uncertain in its outcome.

Our success also will depend, in part, on our refraining from infringing patents or otherwise violating intellectual property owned or controlled by others. Pharmaceutical companies, biotechnology companies, universities, research institutions, and others may have filed patent applications or have received, or may obtain, issued patents in the United States or elsewhere relating to aspects of our technology. It is uncertain whether the issuance of any third-party patents will require us to alter our products or processes, obtain licenses, or cease certain activities. Some third-party applications or patents may conflict with our issued patents or pending applications. Any such conflict could result in a significant reduction of the scope or value of our issued or licensed patents.

In addition, if patents issued to other companies contain blocking, dominating or conflicting claims and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative non-infringing technology and cease practicing those activities, including potentially manufacturing or selling any products deemed to infringe those patents. If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from pursuing the development and commercialization of certain of our potential products. Our failure to obtain a license to any technology that we may require to commercialize our products on favorable terms may have a material adverse impact on our business, financial condition and results of operations.

Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of the proprietary rights of others. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any third party would be found to infringe our patents.

In addition, if our competitors filed patent applications in the United States that claim technology also claimed by us, and such applications were filed before the Leahy-Smith Act took effect, we may have to participate in interference proceedings to determine priority of invention. These proceedings, if initiated by the USPTO, could result in substantial cost to us, even if the eventual outcome is favorable to us. Such proceedings can be lengthy; are costly to defend and involve complex questions of law and fact, the outcomes of which are difficult to predict. An adverse outcome with respect to a third-party claim or in an interference proceeding could subject us to significant liabilities, require us to license disputed rights from third parties, or require us to cease using such technology, any of which could have a material adverse effect on our business, financial condition and results of operations.

We also rely on trade secrets to protect technology, especially where patent protection is not believed to be appropriate or obtainable or where patents have not issued. We attempt to protect our proprietary technology and processes, in part, with confidentiality agreements and assignment of invention agreements with our employees and confidentiality agreements with our consultants and certain contractors. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will

not otherwise become known or be independently discovered by competitors. We may fail in certain circumstances to obtain the necessary confidentiality agreements, or their scope or term may not be sufficiently broad to protect our interests.

If our trade secrets or other intellectual property becomes known to our competitors, it could result in a material adverse effect on our business, financial condition and results of operations. To the extent that we or our consultants or research collaborators use intellectual property owned by others in work for us, disputes may also arise as to the rights to related or resulting know-how and inventions.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States.

These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries, particularly some developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Relating to Our Exposure to Litigation

We are exposed to potential product liability or similar claims, and insurance against these claims may not be available to us at a reasonable rate in the future.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and commercial sale of human therapeutic products. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper administration of the product candidate, or other factors. Many of these patients are already seriously ill and are therefore particularly vulnerable to further illness or death. In addition, healthy volunteers in our indoximod clinical trial or our Ebola vaccine product candidate clinical trial may suffer, or perceive themselves to suffer, personal injury or death related to the Ebola vaccine product candidates and may initiate legal action against us.

We currently carry clinical trial liability insurance in the amount of $5.0 million in the aggregate for claims related to our product candidates other than our Ebola vaccine product candidate. We currently carry clinical trial liability insurance in the amount of $10.0 million in the aggregate for claims related to our Ebola vaccine product candidate. We additionally currently carry clinical trial coverage in lower aggregate amounts in local markets where our clinical trials are conducted on a selective, trial by trial basis. There can be no assurance that we will be able to maintain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance. In addition, there can be no assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be

sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any future products by us or our collaborators.

On December 9, 2014, the HHS declared our Ebola vaccine product candidate covered under the Public Readiness and Emergency Preparedness Act. This declaration provides immunity under U.S. law against legal claims related to the manufacturing, testing, development, distribution and administration of our vaccine candidate. It does not generally provide immunity for a claim brought in a court outside the United States.

Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

We are involved in a securities class-action litigation and are at risk of additional similar litigation in the future that could divert management's attention and adversely affect our business and could subject us to significant liabilities.

In the past, securities class action litigation has often been brought against a company following periods of volatility in the market price of securities. We are a party to the securities class action litigation described in Part II, Item 1 of this Annual Report on Form 10-K under the heading "Legal Proceedings." The defense of this litigation may increase our expenses and divert our management's attention and resources and any unfavorable outcome could have a material adverse effect on our business and results of operations. Any adverse determination in this litigation, or any amounts paid to settle this litigation could require that we make significant payments. In addition, we may in the future be the target of other securities class actions or similar litigation.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and could decline significantly.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including those described elsewhere in this "Risk Factors" section of this Annual Report on Form 10-K and the following:

- new products, product candidates or new uses for existing products introduced or announced by our strategic collaborators, or our competitors, and the timing of these introductions or announcements;
- actual or anticipated results from and any delays in our clinical trials, as well as results of regulatory reviews relating to the approval of our product candidates;
- variations in the level of expenses related to any of our product candidates or clinical development programs, including those relating to the timing of invoices from, and other billing practices of, our clinical research organizations and clinical trial sites;
- expenses related to, or our ability or perceived ability to secure, an adequate supply of any future products approved for commercial sale;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures and capital commitments;
- the commercial or clinical success or failure, or perceived success or failure, of our collaborators, including Merck;

- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- media attention, or changes in media attention, given to cancer and cancer treatment, the recent Ebola epidemic and efforts to develop treatments and vaccines for Ebola, or any other condition or disease that our product candidates are being developed to treat;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- the financial projections we may provide to the public, and any changes in these projections or our failure to meet these projections;
- deviations from securities analysts' estimates or the impact of other analyst rating downgrades by any securities analysts who follow our common stock;
- other events or factors, including those resulting from political uncertainty, war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. We are currently party to the securities class action litigation described in Part II, Item 1 of this Annual Report on Form 10-K under the heading "Legal Proceedings." This litigation and others like it that could be brought against us in the future could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of December 31, 2018, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 46.5% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after December 31, 2018. These stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our Board of Directors, future issuances of our common stock or other securities, declarations of dividends on our common stock and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock. In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares may be distributed and subsequently voted.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to meet compliance obligations.

As a public company, we incur significant legal, accounting and other expenses to comply with reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and The NASDAQ Global Market. Meeting the requirements of these rules and regulations entails significant legal and financial compliance costs, makes some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel devote a substantial amount of time to these compliance requirements. In addition, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to publish a report by our management on our internal control over financial reporting. To achieve compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which has been both costly and challenging. To maintain compliance on an ongoing basis, we will need to dedicate internal resources, engage outside consultants and adopt a detailed work plan. Despite our effort, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We do not expect to pay any cash dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking only cash dividends should not purchase our common stock.

Provisions in our certificate of incorporation, our by-laws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our certificate of incorporation, our by-laws or Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. These provisions include:

- the division of our Board of Directors into three classes with staggered, three-year terms;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to call special meetings;
- limitations on the ability of stockholders to remove directors or amend our by-laws; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person that together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

The holdings of our stockholders may be diluted, and the prices of our securities may decrease, by the exercise of outstanding stock options or by future issuances of securities by us.

We may issue additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock or the exercise of stock options would dilute existing investors and could adversely affect the price of our securities. In addition, such securities may have rights senior to the rights of securities held by existing investors.

Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Code.

Sections 382 and 383 of the Code limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. A Section 382 ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change, and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

Based on Section 382 ownership change analyses, we believe that, from our inception through December 31, 2017, we experienced Section 382 ownership changes in September 2001 and March 2003, and BPS experienced Section 382 ownership changes in January 2006 and January 2011. These ownership changes limited our ability to utilize federal net operating loss carryforwards and certain other tax attributes that accrued prior to the respective ownership changes of us and our subsidiaries and may continue to limit our ability to utilize such attributes in the future.

Additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders.

Accounting pronouncements may impact our reported results of operations and financial position.

U.S. GAAP and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new pronouncements or the application of existing pronouncements to changes in our business could significantly alter our reported financial statements and results of operations.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We conduct our primary operations at leased facilities described below.

Location	Operations Conducted	Approximate Square Feet	Lease Expiration Date
Ames, Iowa	Executive offices and research and development	50,160	January 2020 and March 2021
Austin, Texas	Executive and administrative offices	2,686	November 2019
Wayne, Pennsylvania	Clinical, regulatory, and executive offices	3,255	February 2021

We believe that our administrative office space is adequate to meet our needs for the foreseeable future. We also believe that our research and development facilities, together with third-party manufacturing facilities, will be adequate for our on-going activities.

Item 3. LEGAL PROCEEDINGS

In addition to the legal proceedings described in Note 15 to the consolidated financial statements included in Item 8 of this Form 10-K, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASE OF EQUITY SECURITIES

Our common stock is quoted on The NASDAQ Global Market under the symbol "NLNK." The following table sets forth the range of high and low sales prices for our common stock on The NASDAQ Global Market for the periods indicated.

	High	Low
Fiscal 2018		
First Quarter	$ 10.41	$ 6.38
Second Quarter	7.42	3.75
Third Quarter	5.01	2.31
Fourth Quarter	2.60	1.28
Fiscal 2017		
First Quarter	24.85	10.18
Second Quarter		

25.17

5.90

Third Quarter

19.30

6.25

Fourth Quarter

12.91

7.63

As of February 27, 2019, we had 83 stockholders of record of our common stock. The actual number of stockholders may be greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never paid cash dividends. We do not expect to declare or pay any cash dividends on our common stock in the near future. We intend to retain all earnings, if any, to invest in our operations. The payment of future dividends is within the discretion of our board of directors and will depend upon our future earnings, if any, our capital requirements, financial condition and other relevant factors.

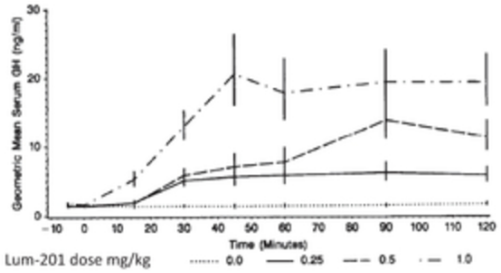
Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Our Stock Performance

The following graph compares cumulative total return of our Common Stock with the cumulative total return of (i) the NASDAQ Stock Market-United States, and (ii) The NASDAQ Biotechnology Index. The graph assumes (a) $100 was invested on November 11, 2011 in our Common Stock, the stocks comprising The NASDAQ Stock Market-United States and the stocks comprising The NASDAQ Biotechnology Index, and (b) the reinvestment of dividends. The comparisons shown in the graph are based on historical data and the stock price performance shown in the graph is not necessarily indicative of, or intended to forecast, future performance of our stock.

* $100 invested on November 11, 2011 in stock or index, including reinvestment of dividends.



Cumulative Total Return

	11/11/2011	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
NewLink Genetics Corporation	$ 100	$ 99	$ 177	$ 311	$ 561	$ 514	$ 145	$ 115	$ 21
NASDAQ Composite	$ 100	$ 97	$						

113

$
156

$
177

$
187

$
201

$
258

$
248

NASDAQ Biotechnology
$
100

$
110

$
145

$
240

$
322

$
358

$
281

$
340

$
308

Date*	Transaction Type	Closing Price**	Beginning No. Of Shares***	Dividend per Share	Dividend Paid	Shares Reinvested	Ending Shares	Cum. Total Return
11/11/2011	Begin	$ 7.08	14.124				14.124	$ 100.0
12/31/2011	Year End	$ 7.04	14.124				14.124	$ 99.4
12/31/2012	Year End	$ 12.50	14.124				14.124	$ 176.6
12/31/2013	Year End	$ 22.01	14.124				14.124	$ 310.9
12/31/2014	Year End	$ 39.75	14.124				14.124	$ 561.4
12/31/2015	Year End	$ 36.39	14.124				14.124	$ 514.0
12/31/2016	Year End	$ 10.28	14.124				14.124	$ 145.0
12/31/2017	Year End	$ 8.11	14.124				14.124	$ 115.0
12/31/2018	Year End	$ 1.52	14.124				14.124	$ 21.0

* Specified ending dates are ex-dividends dates.

** All Closing Prices and Dividends are adjusted for stock splits and stock dividends.

*** ‘Begin Shares’ based on $100 investment.

Recent Sales of Unregistered Securities

None

Repurchases of Equity Securities

During 2018, the Company repurchased 33,761 shares of its common stock at an average price of $8.16 per share. During 2017, the Company repurchased 28,521 shares of its common stock at an average price of $10.11 per share. The repurchase details are presented in the table below.

Period	Total Number of Shares Purchased	Average Price Paid per Share
January 1, 2018 - January 31, 2018	28,720	$ 9.11
June 1, 2018 - June 30, 2018	359	5.10
July 1, 2018 - July 31, 2018	1,015	3.90
August 1, 2018 - August 31, 2018	74	2.89
October 1, 2018 - October 31, 2018	2,484	2.28
November 1, 2018 - November 30, 2018	1,109	2.08
Total	33,761	$ 8.16

Use of Proceeds

Not applicable.

Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with our financial statements and the related notes appearing at the end of this Annual Report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this annual report.

We derived the annual consolidated financial data from our audited consolidated financial statements. The statement of operations data for the years ended December 31, 2018, 2017, and 2016 and the balance sheet data as of December 31, 2018, and 2017 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. We derived the summary consolidated statement of operations data for the years ended December 31, 2015 and 2014 and the balance sheet data as of December 31, 2016, 2015 and 2014 from our audited consolidated financial statements not included in this Annual Report on Form 10-K.

Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
(in thousands, except per share data)					
Statement of operations data:					
Grant revenue	$ 11,268	$ 28,321	$ 32,242	$ 32,358	$ 6,642
Licensing and collaboration revenue	1,206	390	3,526	36,143	

165,950				
Total operating revenue				
12,474	28,711	35,768	68,501	172,592
Operating expenses:				
Research and development	45,694	69,866	93,300	71,414	35,691
General and administrative	29,218	31,726	33,226	30,689	

19,328					
Total operating expenses					
74,912					
101,592					
126,526					
102,103					
55,019					
(Loss) income from operations					
(62,438)					
(72,881)					
(90,758)					
(33,602)					
117,573					
Other income and expense:					
Miscellaneous (expense) income					
(102)					
(126)					
32					
(14)					
—					

Interest income

2,029

616

237

78

86

Interest expense

(52
)

(119
)

(22
)

(105
)

(26
)

Other income (expense), net

1,875

371

247

(41
)

60

Net (loss) income before taxes

(60,563
)

(72,510
)

(90,511
)

(33,643
)

117,633

Income tax benefit (expense)	6,968	559	5,356	(6,738)	(21,616)
Net (loss) income	$ (53,595)	$ (71,951)	$ (85,155)	$ (40,381)	$ 96,017
Basic (loss) earnings per share	$ (1.44)	$ (2.30)	$ (2.94)	$ (1.41)	$ 3.45
Diluted (loss) earnings per share	$ (1.44)	$ (2.30)	$ (2.94)		

$

(1.41

)

$

3.09

Basic average shares outstanding

37,191

31,304

28,979

28,587

27,839

Diluted average shares outstanding

37,191

31,304

28,979

28,587

31,025

	As of December 31,				
	2018	2017	2016	2015	2014
			(in thousands)		
Balance sheet data:					
Cash, cash equivalents, and certificates of deposit	$ 120,738	$ 158,708	$ 131,490	$ 197,800	$ 202,797
Working capital	118,225	153,435	130,007	193,302	198,601
Total assets	130,939	180,697	174,747	218,542	231,221
Royalty obligations, notes payable and obligations under capital leases	6,104	6,271	6,517	6,381	7,133
Accumulated deficit	(291,012)	(237,459)	(165,508)	(80,353)	(39,960)
Total stockholders’ equity	115,143	151,557	129,466	195,744	196,936

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the consolidated financial statements and notes thereto included in Part II, Item 8 of this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K completely.

Overview

We are a clinical-stage immuno-oncology company focused on developing novel immunotherapeutic products for the treatment of patients with cancer. Our leading small-molecule product candidates currently in clinical development target the indoleamine-2, 3-dioxygenase, or IDO, pathway, which is one of the key pathways for cancer immune escape. These product candidates, indoximod and NLG802 (a prodrug of indoximod), are IDO pathway inhibitors with mechanisms of action that center around breaking the immune system's tolerance to cancer. We also have an additional small molecule product candidate, NLG207, which is a nanoparticle-drug conjugate, or NDC, consisting of a cyclodextrin-based polymer backbone conjugated to camptothecin, a topoisomerase 1 inhibitor.

We had a net loss of $53.6 million for the year ended December 31, 2018. We expect to continue to have net losses over the next several years as we advance our product candidates through late-stage clinical trials, pursue regulatory approval of our product candidates, and expand our commercialization activities in anticipation of one or more of our product candidates receiving marketing approval.

Financial Overview

Revenues

We have never earned revenue from commercial sales of any of our product candidates. We generated revenues of $12.5 million for the year ended December 31, 2018. We had grant revenues of $11.3 million attributable to revenues earned for the performance of research and development under contracts and grants with the Department of Defense, or DOD, and BARDA. We also earned license and collaboration revenues of $1.2 million, which consisted of revenues recognized under the license and collaboration agreement with Merck entered into during 2014.

In the future, we may generate revenue from a variety of sources, including product sales if we develop products which are approved for sale, license fees, milestones, research and development and royalty payments in connection with strategic collaborations or government contracts, or licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research and development reimbursements, milestone and other payments we may receive under potential strategic collaborations, and the amount and timing of payments we may receive upon the sale of any products, if approved, to the extent any are successfully commercialized. We do not expect to generate revenue from product sales for several years, if ever. If we fail to complete the development of our product candidates in a timely manner or to obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expenses

Research and development expenses consist of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of:

- employee-related expenses, which include salaries, bonuses, benefits and share-based compensation;
- the cost of acquiring and manufacturing clinical trial materials;

- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- facilities, depreciation of fixed assets and other allocated expenses, which include direct and allocated expenses for rent and maintenance of research facilities and equipment;
- license fees for and milestone payments related to in-licensed products and technology; and
- costs associated with non-clinical activities and regulatory approvals.

We expense research and development expenses as incurred.

Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, duration and complexity of later stage clinical trials. We plan to continue to incur significant research and development expenses for the foreseeable future as we continue to seek regulatory approval and exclusivity for indoximod, further advance our earlier-stage research and development projects and strengthen our pipeline of immune stimulatory product candidates through our clinical and business development programs. For the years ended December 31, 2018, 2017 and 2016 we incurred $45.7 million, $69.9 million, and $93.3 million, respectively, in research and development expenses.

The following table summarizes our research and development expenses by category of costs for the periods indicated:

Research and Development Expenses by Category
(In thousands)

	Years Ended December 31,		
	2018	**2017**	**2016**
Compensation	$ 16,099	$ 18,873	$ 21,905
Equipment, supplies and occupancy	3,244	6,246	14,073
Outside clinical and other	26,351	44,747	57,322
Total research and development expenses	$ 45,694	$ 69,866	$ 93,300

At this time, we cannot accurately estimate or know the nature, specific timing or costs necessary to complete clinical development activities for our product candidates. We are subject to the numerous risks and uncertainties associated with developing biopharmaceutical products including the uncertain cost and outcome of ongoing and planned clinical trials, the possibility that the FDA or another regulatory authority may require us to conduct clinical or non-clinical testing in addition to trials that we have planned, rapid and significant technological changes, frequent new product and service introductions and enhancements, evolving industry standards in the life sciences industry and our future need for additional capital. In addition, we currently have limited clinical data concerning the safety and efficacy of our product candidates. A change in the outcome of any of these variables with respect to the development of any of our product candidates could result in a significant change in the costs and timing of our research and development expenses.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, information technology, legal and human resources functions. Other general and administrative expenses include facility costs not otherwise associated with research and development expenses, intellectual property prosecution and defense costs and professional fees for legal, consulting, auditing and tax services.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash and cash equivalents and certificates of deposit. The primary objective of our investment policy is capital preservation. We expect our interest income to decrease as we invest in our clinical development activities and operations.

Interest expense consists primarily of interest, amortization of debt discount and amortization of deferred financing costs associated with our notes payable and obligations under capital leases.

Restructuring Charges

In July 2018, we completed an organizational review of our clinical programs and reduced our headcount by approximately 30% as compared to June 30, 2018 and made several changes to senior leadership effective July 26, 2018 in order to conserve resources.

In July 2017, we undertook an organizational realignment to refocus our clinical development efforts and align our resources to focus on our highest value opportunities. The restructuring activities included a reduction of our workforce by approximately 50%, which consisted primarily of clinical and research and development staff, as well as stopping additional research on the Zika virus.

In May 2016, we announced that our Phase 3 clinical trial IMPRESS, for algenpantucel-L, which utilizes our HyperAcute Cellular Immunotherapy technology, failed to achieve its primary endpoint. As a result, we adopted a restructuring plan designed to better align our workforce and operating costs to our revised pipeline development plans and operating needs. The restructuring plan included a reduction in our workforce; the exit of or reduction of certain leased facilities; and the renegotiation or termination of contracts with certain third parties. In connection with the restructuring plan, we also discontinued the development of our commercial manufacturing capabilities for algenpantucel-L, discontinued programs supporting the future commercialization of algenpantucel-L and recorded an impairment charge to fixed assets. We have retained some internal manufacturing ability to support the development of clinical supplies for our ongoing clinical trials of the other HyperAcute Cellular Immunotherapy product candidates.

Restructuring charges of $1.3 million, $1.7 million, and $11.6 million were recorded during the years ended December 31, 2018, 2017 and 2016, respectively, relating to these reorganizations. Refer to Note 14 for more information.

Income Tax Benefit and Expense

For the years ended December 31, 2018, 2017 and 2016, we had an income tax benefit of $7.0 million, $559,000, and $5.4 million, respectively. Income tax differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to the loss incurred for our foreign subsidiary and the ability to carry back current year losses to prior years and limitations on the ability to carry 2017 losses back to 2015. In addition, for the year ended December 31, 2018 the tax differs from the statutory U.S. federal tax rate due to amendments filed for certain states for the years ending December 31, 2014 and 2015.

The valuation allowance for deferred tax assets as of December 31, 2018 and 2017 was $62.0 million and $50.2 million, respectively. The net change in the total valuation allowance for the years ended December 31, 2018 and 2017 was an increase of $11.8 million. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “Tax Act”). The Tax Act repealed the corporate AMT for years beginning January 1, 2018, and provides that existing AMT credit carryovers are partially refundable beginning in 2018 as an offset to a taxable liability, with full refunds beginning in 2021. We have approximately $140,000 of AMT credit carryovers that are expected to be fully refunded by 2021. The Tax Act had no other material impacts to the consolidated financial statements upon enactment. For all other net deferred tax assets as of December 31, 2018 and 2017, a full valuation allowance has been established due to the uncertainty of future recoverability.

As of December 31, 2018 and December 31, 2017, we had federal net operating loss carryforwards of $74.5 million and $38.8 million and federal research credit carryforwards of $28.3 million and $26.2 million, respectively. Sections 382 and 383 of the Code limit a corporation’s ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporation’s business, results of operations, financial condition and cash flow.

Based on analysis, we believe that, from our inception through December 31, 2017, we experienced Section 382 ownership changes in September 2001 and March 2003 and one of our subsidiaries experienced Section 382 ownership changes in January 2006 and January 2011. These ownership changes limited our ability to utilize federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the respective ownership changes of us and one of our subsidiaries.

Even if another ownership change has not occurred, additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or certain changes in the ownership of any of our 5% stockholders.

Critical Accounting Policies and Significant Judgments and Estimates

We have prepared our audited consolidated financial statements in accordance with United States generally accepted accounting principles, or U.S. GAAP. Our preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the financial statements, as well as revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions. We have reviewed our critical accounting policies and estimates with the Audit Committee of our Board of Directors.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements included later in this annual report, we believe the following accounting policies to be critical in the preparation of our financial statements.

Expenses Accrued Under Contractual Arrangements with Third Parties; Accrued Clinical Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period, which is based on an established protocol specific to each clinical trial. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period.

Share-Based Compensation

We are required to estimate the grant-date fair value of stock options, stock awards and restricted stock issued to employees and recognize this cost over the period these awards vest. We estimate the fair value of each stock option granted using the Black-Scholes option pricing model. The Black-Scholes model requires the input of assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs. Generally, we have issued stock options that vest over time. For these awards, we record compensation cost on a straight-line basis over the vesting period. Generally, we issue awards that vest either monthly or vest 25% on the first anniversary date of issuance with the remaining

options vesting ratably over the next 36 months, or as determined by the Board of Directors at the time of grant. We calculate the fair value of the award on the grant date, which is the date the award is authorized by the Board of Directors or Chief Executive Officer and the employee has an understanding of the terms of the award.

The fair value of restricted stock units, or RSUs, are subject to cliff vesting are recognized as compensation expense over the requisite service period using the straight line attribution method, and the fair value of RSUs that are subject to graded vesting are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of performance share units are recognized as compensation expense beginning at the time in which the performance conditions are deemed probable of achievement, over the remaining requisite service period.

We recorded noncash share-based compensation expense for employee and nonemployee stock options and restricted stock awards of $17.1 million, $18.5 million and $16.7 million during 2018, 2017 and 2016, respectively. As of December 31, 2018, the total compensation cost related to unvested option awards and restricted stock awards not yet recognized was $8.3 million and $1.0 million, respectively, and the weighted average period over which the expenses are expected to be recognized are 2.1 years and eleven months, respectively. We expect to continue to grant stock options and restricted stock awards in the future, which will increase our share-based compensation expense in future periods. If any of the assumptions used in the Black-Scholes model change significantly, share-based compensation expense for new awards or awards to nonemployees may differ materially in the future from that recorded in the current period for awards previously granted.

The following table summarizes our assumptions used in the Black-Scholes model for option grants during the last three years:

Black-Scholes Model Assumptions

	Years Ended December 31,		
	2018	2017	2016
Exercise price	$2.27-$8.56	$6.75-$23.09	$10.31-$34.73
Risk-free interest rate	2.61%-3.02%	1.91%-2.22%	1.19%-1.97%
Expected dividend yield	—	—	—
Expected volatility	76.2%-79.3%	68.9%-76.9%	67.1%-69.8%
Expected term (in years)	4.0-7.9	1.2-7.8	5.9-7.4

Exercise Price. We use the quoted market price as listed on the public exchange on the date of grant.

Expected Volatility. We use our historical stock price volatility. The volatility is calculated over a period of time commensurate with the expected term for the options granted.

Expected Term (in Years). The expected term of a stock option is the period of time for which the option is expected to be outstanding. We use historical exercise and option expiration data to estimate the expected term for the Black-Scholes grant-date valuation.

Risk-Free Interest Rate. We use the average yield on current U.S. Treasury instruments with terms that approximate the expected term of the stock options being valued.

Expected Dividend Yield. The expected dividend yield for all of our stock option grants is 0%, as we have not declared a cash dividend since inception, and do not expect to do so in the foreseeable future.

Forfeitures. The share-based compensation expense recognized has been reduced for estimated forfeitures. The estimated forfeiture rate is based on historical experience of our option plan, which we expect to continue at the current level, and any adjustments in the forfeiture rate in the future will result in a cumulative adjustment in the period that this estimate is changed. Ultimately, the total compensation expense recognized for any given share-based award over its vesting period will only be for those shares that actually vest.

Common Stock Fair Value. The fair value of the common stock is the quoted market price as listed on the NASDAQ Global Market.

Based on the per share closing price of our common stock on the NASDAQ Global Market of $1.52 per share on December 31, 2018, the intrinsic value of stock options outstanding at December 31, 2018, was $2,357, all of which related to stock options that were vested at that date.

Revenue Recognition

Revenues in 2018 are recognized under Topic 606 when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. We receive payments from government entities under our grants and contracts with the Department of Defense and the United States Department of Health and Human Services, or HHS. These agreements provide us cost reimbursement plus a percentage for certain types of expenditures in return for research and development activities over a contractually defined period. Grant revenues are recognized over time and measured using the input method. We use labor costs and subcontractor fees as inputs to measure progress towards satisfying its performance obligations under these agreements. This is the most faithful depiction of the transfer of goods and services to the government entities due to the government entities' control over the research and development activities. Under this method, we recognize revenue generally in the period during which the related costs are incurred, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services.

See Note 7, License and Research Collaboration Agreements, to the accompanying audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further information.

Income Taxes

Income taxes are recorded for the amount of taxes payable for the current year and include deferred tax assets and liabilities for the effect of temporary differences between the financial and tax basis of recorded assets and liabilities using enacted tax rates. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized. Income tax was a benefit of 11.5% of our loss before income taxes in 2018. A valuation allowance of $62.0 million as of December 31, 2018 offsets our net deferred tax assets.

The Company considers accounting for income taxes critical to our operations because management is required to make subjective judgments in developing our provision for income taxes, including the determination of deferred tax assets and liabilities, any valuation allowances that may be required against deferred tax assets, and reserves for uncertain tax positions.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

Revenues. Revenues for the year ended December 31, 2018 were $12.5 million, as compared to $28.7 million in 2017, a decrease of $16.2 million. Grant revenue decreased by $17.1 in 2018 due to a decrease in billings under the government grant contracts as a result of transferring our obligation as prime contractor on the agreements to Merck in 2018. Licensing and collaboration revenues increased by $816,000 due to higher revenues recognized under the Merck Agreement in 2018.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2018 were $45.7 million, decreasing from $69.9 million for the same period in 2017. The $24.2 million decrease was due primarily to reductions of $15.2 million in contract research and manufacturing expense, $3.0 million in personnel-related expense, $3.3 million in supplies and equipment, $1.8 million in clinical trial costs, $1.3 million in technology and licensing, and a reduction in restructuring expenses of $100,000, offset by a $500,000 increase in consulting and other costs.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2018 were $29.2 million, decreasing from $31.7 million for the same period in 2017. The $2.5 million decrease was due to a reduction of $2.5 million in personnel-related spend, a $550,000 reduction in consulting and other costs, and a reduction in restructuring expenses of $300,000, offset by an $850,000 increase in supplies and other expense.

Income Tax Benefit/Expense. Income tax for the year ended December 31, 2018 was a benefit of $7.0 million compared to an income tax benefit of $559,000 for the same period in 2017. The increase in the benefit is primarily due to amendments filed in 2018 for certain states for the years ending December 31, 2014 and 2015.

Net Loss. Net loss for the year ended December 31, 2018 was $53.6 million, a decrease from the net loss of $72.0 million for the same period in 2017 primarily due to the decrease in operating expenses, the increase in the income tax benefit, offset by the decrease in revenues. The diluted average shares outstanding for 2018 were 37.2 million, resulting in diluted loss per share of $1.44, as compared to 31.3 million diluted average shares outstanding and $2.30 a diluted loss per share for 2017.

Comparison of the Years Ended December 31, 2017 and 2016

Revenues. Revenues for the year ended December 31, 2017 were $28.7 million, as compared to $35.8 million in 2016, a decrease of $7.1 million. Grant revenue decreased by $3.9 million in 2017 due to a decrease in billings under the government contracts. Licensing and collaboration revenues decreased by $3.1 million due to lower revenues recognized under the Genentech and Merck Agreements in 2017.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2017 were $69.9 million, decreasing from $93.3 million for the same period in 2016. The $23.4 million decrease was due primarily to higher restructuring charges of $11.1 million incurred in 2016, including a non-cash charge of $4.0 million related to impaired assets, as compared to $600,000 of charges incurred in 2017. Remaining decreases included $6.2 million in clinical trial costs, $4.4 million in supplies, equipment and licensing, $3.6 million in personnel-related expense and $200,000 in manufacturing expense, offset by increases of $1.0 million in stock compensation expense and $600,000 in legal and consulting.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2017 were $31.7 million, decreasing from $33.2 million for the same period in 2016. The $1.5 million decrease was due to a $2.3 million reduction in personnel-related spend and decrease of $1.2 million in legal and consulting, offset by increases of $700,000 in stock compensation expense, $700,000 in supplies and equipment, and $600,000 in restructuring charges incurred in 2017.

Income Tax Benefit/Expense. Income tax benefit for the year ended December 31, 2017 was $559,000, compared to an income tax benefit of $5.4 million for the same period in 2016. The change is primarily due to the limited ability to carry 2017 losses back to 2015 compared to the larger benefit of $6.0 million generated by the ability to carry 2016 losses back to 2014. Our income tax benefit for the year ended December 31, 2017 was increased by the release of the valuation allowance previously recorded against the deferred income tax benefit for $140,000 in AMT credits as a result of the Tax Act. Our 2016 income tax benefit was reduced by amounts recorded for uncertain tax positions.

Net Loss. Net loss for the year ended December 31, 2017 was $72.0 million, a decrease from net loss of $85.2 million for the same period in 2016, primarily due to the decrease in operating expenses, offset by the decrease in revenues and the decrease in income tax benefit. The diluted average shares outstanding for 2017 were 31.3 million, resulting in diluted loss per share of $2.30, as compared to 29.0 million average shares outstanding and $2.94 diluted earnings per share for 2016.

Liquidity and Capital Resources

Before our initial public offering, or IPO, in 2011 we funded our operations principally through the private placement of equity securities, debt financing and interest income. We received aggregate proceeds, net of offering costs, of $76.3 million from the issuance of convertible preferred stock from inception through 2011. Since our IPO, in 2011, we have funded our operations principally through public offerings of common stock and payments under our collaboration agreements and government contracts. In our IPO, we received net proceeds, of $37.6 million. In February 2013 we received net proceeds of $49.0 million in an underwritten public offering. Between September 2013 and March 2015, we raised a total of $58.7 million in net proceeds under an ATM Offering with Cantor Fitzgerald & Co., or Cantor. We launched another ATM offering with Cantor in June 2017 under which we have sold 1,940,656 shares of the Company’s common stock for aggregate net proceeds of $19.3 million after commissions of $398,000 paid to Cantor and other costs of $163,000 as of December 31, 2017.

On October 6, 2017, we successfully raised proceeds of $55.2 million, net of offering costs of $3.7 million, from the issuance of 5,750,000 shares of our common stock in an underwritten public offering.

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

Sources and Uses of Cash
(In thousands)

	Years Ended December 31,		
	2018	2017	2016
Net cash used in operating activities	$ (37,939)	$ (48,281)	$ (65,947)
Net cash provided by (used in) investing activities	117	211	(66)
Net cash (used in) provided by financing activities	(148)	75,288	1,883
Net (decrease) increase in cash and cash equivalents	$ (37,970)	$ 27,218	$ (64,130)

For the year ended December 31, 2018, we used cash of $37.9 million in our operating activities. Net cash used in operating activities decreased $10.3 million during 2018 as compared to 2017, primarily due to the $18.4 million decrease in net loss, net of non-cash items, and the $8.1 million increase in working capital.

For the year ended December 31, 2016, the sources and uses of cash was driven primarily by the decrease in licensing and collaboration revenues and decrease in income tax expense, offset by increases in operating expenses.

For the years ended December 31, 2018, 2017 and 2016, our investing activities generated cash of $117,000, and cash of $211,000, and used cash of $66,000, respectively. The cash provided by investing activities in the year ended December 31, 2018 was due to the proceeds received from sales of property and equipment of $124,000, offset by $7,000 in purchases of property and equipment. The cash provided by investing activities in the year ended December 31, 2017 was due to the proceeds received from sales of property and equipment of $254,000, offset by $43,000 in purchases of property and equipment. The cash used by investing activities in the year ended December 31, 2016 was due to the maturity of our certificates of deposit for $2.2 million, offset by $2.3 million in purchases of property and equipment.

For the years ended December 31, 2018, 2017 and 2016, our financing activities used cash of $148,000, and provided cash of $75.3 million and $1.9 million, respectively. The cash used in financing activities in the year ended December 31, 2018 was primarily due to the repurchase of common stock of

$275,000 and payments on capital lease obligations and notes payable of $167,000, offset by the sale and issuance of common stock for net proceeds of $294,000. The cash provided by financing activities in the year ended December 31, 2017 was primarily due to the sale and issuance of common stock for net proceeds of $75.8 million, offset by the repurchase of common stock of $289,000 and payments on capital lease obligations and notes payable of $246,000. The cash provided by financing activities in the year ended December 31, 2016 was primarily due to the sale and issuance of common stock for net proceeds of $2.2 million, offset by the repurchase of common stock of $82,000 and net payments on long-term obligations of $257,000.

Obligations under our Royalty and Loan Agreements

March 2005 and March 2012 Iowa Economic Development Authority Loan

In March 2005, we entered into a $6.0 million forgivable loan agreement with the Iowa Department of Economic Development, or the IDED. Under the agreement, in the absence of default, there were no principal or interest payments due until the completion date for the project. The agreement provided us with financial assistance for research and product development activities at our Iowa State University Research Park facility. Additionally, under the agreement, we were obligated to pay a minimum of 0.25% royalties on all gross revenues of any products that we bring to market with a cumulative maximum royalty amount due of $3.2 million. Substantially all of our assets were pledged to secure this loan. This loan was converted into a royalty obligation under the terms of a settlement agreement entered into on March 26, 2012, or the IEDA Agreement, with the Iowa Economic Development Authority, or the IEDA, as successor in interest to the IDED.

March 2012 IEDA Royalty Obligation

Under the terms of the IEDA Agreement, the forgivable loan agreement between us and IEDA (as successor to IDED) was terminated and we were thereby released from the forgivable loan agreement’s job creation, project expenditure, royalty and other requirements in exchange for agreeing to pay a royalty of 0.50% on all gross revenues

of any products that we bring to market, with a cumulative maximum royalty obligation due of $6.8 million. Additionally, under the IEDA Agreement, the IEDA released its security interest in our assets. We are obligated to maintain our business substantially in the State of Iowa until the royalty obligation under the IEDA Agreement is satisfied.

2009 and 2012 Iowa State University Research Park Loans

In 2009, we executed a promissory note in favor of Iowa State University Research Park, or ISURP, in an original principal amount of $800,000, which was due in monthly installments through March 2018. The note represents amounts owed by us to ISURP for certain improvements that were made to facilities we lease from ISURP. The principal and interest owed under the note is amortized over an eight-year period. Interest is payable monthly under this promissory note, initially at a rate of 3.0% per annum and increasing to 5.0% per annum after five years from the date the improvements were completed. ISURP may accelerate all amounts owed under the note upon an event of default, including our uncured material breach of the terms of the note or the lease or upon early termination of the lease. In the event of a default under the note, amounts owed under the note will bear interest at 8.0% per annum. The balance outstanding under the 2009 note was $0 and $29,000 at December 31, 2018 and December 31, 2017, respectively.

In 2012, we executed a promissory note in favor of ISURP in an original principal amount of $456,000, which is due in monthly installments through September 2020. The note represents amounts owed by us to ISURP for certain additional improvements that were made to facilities we lease from ISURP. The principal and interest owed under the note is amortized over an eight-year period. Interest is payable monthly under this promissory note, initially at a rate of 3.0% per annum and increasing to 5.0% per annum after five years from the date the improvements were completed. ISURP may accelerate all amounts owed under the note upon an event of default, including our uncured material breach of the terms of the note or the lease or upon early termination of the lease. In the event of a default under the note, amounts owed under the note will bear interest at 8.0% per annum. The balance outstanding under the 2012 note was $111,000 and $169,000 at December 31, 2018 and December 31, 2017, respectively.

March 2010 City of Ames Forgivable Loan

In March 2010, we entered into a $400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, jointly, as lenders. The project provides us with financial assistance to construct new facilities within the Ames city limits. In the absence of a default, there were no principal or interest payments due until March 10, 2016.

The project required us to create or retain at least 150 full-time jobs located in Ames, Iowa by March 10, 2016. The agreement required us to enter into a five-year building lease with the option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015, which requirement was met prior to the March 10, 2015 deadline. As of March 10, 2016, the Company had satisfactorily fulfilled all of the above terms of the loan agreement and the loan was forgiven. Accordingly, the entire outstanding loan amount of $397,000 was derecognized with a corresponding amount recorded in grant revenue for the year ended December 31, 2016.

Operating Capital Requirements

We anticipate that we will continue to generate significant operating losses for the next several years as we incur expenses to advance our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

We may seek to sell additional equity or debt securities or obtain a credit facility if our available cash and cash equivalents are insufficient to satisfy our liquidity requirements or if we develop additional opportunities to do so. The sale of additional equity and debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with research, development and commercialization of biopharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of clinical trials for our product candidates, and discovery and development activities related to new product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales, facilities, and distribution costs;
- the cost of manufacturing our product candidates and any products we commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- whether, and to what extent, we are required to repay our outstanding government provided loans;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2018:

Contractual Obligations Due
(In thousands)

	Total	**Less than 1 Year**	**1 to 3 Years**	**3 to 5 Years**	**More than 5 Years**
Short and long-term debt (including interest)[1]	$ 6,116	$ 66	$ 50	$ —	$ 6,000
Operating lease obligations	11,417	1,105	1,926	1,816	6,570

Total contractual cash obligations	$ 17,533	$ 1,171	$ 1,976	$ 1,816	$ 12,570

(1) Short and long-term debt includes an accrued royalty obligation of $6.0 million for which the timing of payment is uncertain. See section *"March 2012 IEDA Royalty Obligation"* above.

Under the license agreements described below under the heading "Financial Obligations Related to Licensing and Development — In-Licensing Agreements" we are obligated to make potential milestone payments as listed in the following table. These obligations are contingent upon achieving the applicable milestone event, the timing of which cannot presently be determined.

Licensor	Aggregate potential milestone payments
Augusta University Research Institute under AURI IDO Agreement	$2.8 million per licensed product
Public Health Agency of Canada	$250,000

We incurred expense of approximately $32,000, $1.4 million, and $2.0 million, under all of the in-licensing agreements for the years ended December 31, 2018, 2017, and 2016, respectively.

Financial Obligations Related to Licensing and Development

In-Licensing Agreements

We are subject to a number of licensing agreements with respect to certain of the technologies that underlie our intellectual property. Unless otherwise noted, these agreements typically provide that we have exclusive rights to the use and sublicensing of the technologies in question for the duration of the intellectual property patent protection in question, subject to us meeting our financial and other contractual obligations under the agreements. Certain of the key licensing agreements with significant financial obligations include the following:

Augusta University Research Institute-IDO. We are a party to a License Agreement dated September 13, 2005, or the AURI IDO Agreement, with Augusta University Research Institute, or AURI, which was formerly known as Georgia Regents Research Institute, the Georgia Health Sciences University Research Institute, Inc. and the Medical College of Georgia Research Institute. The AURI IDO Agreement was amended on March 28, 2006, April 27, 2006, February 13, 2007, July 12, 2013, July 10, 2014 and March 15, 2016. The AURI IDO Agreement grants us, including our affiliates, an exclusive, worldwide license, under specified AURI patent rights and related technology to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology in all medical applications.

In consideration of such license grant, we have paid AURI specified license fees (including issuing shares of our common stock) and have made certain investments toward the further development of licensed products within the specified time periods, and we are obligated to pay to AURI annual license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $2.8 million per licensed product, and royalties as a single-digit percentage of net sales of the licensed products, subject to minimum royalty payments and royalty rates depending on the type of license product. In addition, if we grant a sublicense under the license granted by AURI, we must pay to AURI a percentage of the consideration we receive from the sublicensee.

The Genentech Agreement. In October 2014, we entered into the Genentech Agreement for the development and commercialization of NLG919, our clinical stage IDO pathway inhibitor, and a research collaboration for the discovery of next generation IDO/TDO inhibitors to be developed and commercialized under the Genentech Agreement. On June 6, 2017, we received a formal notice of Genentech's intent to terminate the Genentech Agreement with respect to NLG919. As part of the partial termination, worldwide rights to NLG919 reverted to us, and Genentech granted to us an exclusive, royalty-bearing license under certain Genentech intellectual property to develop and commercialize NLG919. If NLG919 is commercialized, we will be obligated to pay to Genentech royalties as a low single-digit percentage of net sales of NLG919.

Public Health Agency of Canada Agreement. BPS is a party to a license agreement with PHAC, dated May 4, 2010, which was amended and restated December 5, 2017, or the PHAC License. Under the terms of the PHAC License, BPS has a worldwide, personal, non-transferable, sole, revocable, royalty-bearing license under specified patent rights and know-how, for the development and commercialization of products directed to the prevention, prophylaxis and treatment of Ebola (Zaire), a rVSV based on viral hemorrhagic fever, or VHF virus, and a worldwide, personal, non-transferable, non-exclusive, revocable, royalty-bearing license, under specified patent rights and know-how, for the development and commercialization of products directed to the prevention, prophylaxis and treatment of Ebola (Sudan), a VHF virus.

In consideration of the license grants, BPS must pay to Canada, annual license maintenance fees, patent prosecution costs, potential milestone payments in an aggregate amount up to approximately C$250,000, and royalties as a low single-digit percentage of the sales price of the licensed products sold by BPS, its affiliates or sublicensees in countries outside of Africa and GAVI eligible countries, which royalty rate varies depending on whether additional technology licenses are required to sell the licensed product, and whether the licensed product is covered by a valid claim of a patent licensed under the PHAC License. In addition to the milestones discussed above, BPS is required to pay to Canada a percentage in the low double digits of certain consideration BPS receives from Merck or any other sublicensee over specified thresholds. BPS is obligated to use commercially reasonable efforts to develop and market the licensed products.

Collaborative Agreements with Medical Institutions

We have entered into numerous agreements with various medical institutions for the performance of clinical trials for various products in the past. They typically require the payment of fees by us for the performance of the clinical trials and the maintenance of confidentiality as to the associated technology. We may enter into additional agreements in the future.

Patents and Trademarks

As noted above, we presently have an extensive portfolio of patents and patent applications (and certain trademark registrations) with the United States Patent and Trademark Office. During the years ended December 31, 2018, 2017 and 2016, we incurred expenses related to the filing, maintenance, and initiation of our patent portfolio of $828,000, $411,000, and $196,000, respectively, for an increase of 100% for the 2018 period as compared to the same period in 2017, and an increase of 110% for the 2017 period as compared to the same period in 2016. Increased costs in 2018 compared to 2017 were due to increased activity on new filings and pending cases. Increased costs in 2017 compared to 2016 were due to increased activity on pending cases.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02 (Topic 842), Leases, to improve financial reporting for leasing transactions. We will adopt the standard on January 1, 2019 using the modified retrospective method, as required, applying the new standard to all leases existing as of the date of initial application. We have elected the date of initial application will be the effective date, or January 1, 2019. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. The new standard provides a number of optional practical expedients in transition. We expect to elect the ‘package of practical expedients’, which permits us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs. We do not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to us.

We expect that this standard will have a material effect on our consolidated balance sheet due to the recognition of right-of-use assets and lease liabilities. While we continue to assess all of the effects of adoption, we expect it to primarily relate to the operating leases for office and laboratory space noted in “Part I. Item 2. Properties” of this Annual Report on Form 10-K, for which we will record a lease liability and corresponding right-of-use asset upon adoption. The lease liability will equal the present value of unpaid minimum lease payments for operating leases that exist as of the date of initial application of the new standard. Future undiscounted obligations related to facility leases in effect as of the date of initial application of the new standard are included in the table of future minimum lease payments as disclosed and aggregate to $11.4 million.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of December 31, 2018 and December 31, 2017, we had cash and cash equivalents of $120.7 million and $158.7 million, respectively, consisting of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable securities. Our certificates of deposit are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We expect to have the ability to hold our certificates of deposit until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

Our long-term debt and our capital lease obligations bear interest at fixed rates. Any change in interest rates would have an immaterial (or no) impact on our financial statements.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The report of KPMG LLP, our independent registered public accounting firm, the financial statements of us and our consolidated subsidiaries and the notes thereto are included beginning on page F-1.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation required by the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the supervision and with the participation of our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act, as of December 31, 2018. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2018, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC and to provide reasonable assurance that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2018 based on criteria established in *Internal Control — Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. As a result of this assessment, management concluded that, as of December 31, 2018, our internal control over financial reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Our internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of our internal control over financial reporting as of December 31, 2018, was audited by our independent registered public accounting firm, KPMG LLP, as stated in its report, which is included in this filing on page B-68.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls.

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all internal control issues and instances of fraud, if any, have been detected.

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item concerning our directors and nominees is incorporated by reference to our definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, or the 2019 Proxy Statement.

Item 11. EXECUTIVE COMPENSATION

The information required by this item concerning the compensation of our directors and executive officers is incorporated by reference to the 2019 Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item concerning securities authorized under our equity compensation plans and security ownership of certain beneficial owners is incorporated by reference to the 2019 Proxy Statement.

Securities Authorized For Issuance Under Equity Compensation Plans

We maintain our 2009 Equity Incentive Plan, 2010 Non-Employee Directors' Stock Award Plan and 2010 Employee Stock Purchase Plan, each of which was approved by the Company's security holders, pursuant to which we may grant equity awards to eligible persons.

The following table gives information about equity awards under the foregoing plans as of December 31, 2018:

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by security holders	8,048,229	$ 12.08	1,930,807 (1)(2)
Equity compensation plans not approved by security holders	—	$ .00	—
Total	8,048,229	$ 12.08	1,930,807

(1) The 2009 Equity Incentive Plan incorporates an evergreen formula pursuant to which, on each January 1st, the aggregate number of shares reserved for issuance under the plan will increase by a number equal to 4% of the outstanding shares on December 31st of the preceding calendar year, or such lesser amount (or no shares) as determined by our Board.

(2) Of these shares, as of December 31, 2018, 1,877,298 shares remained available under the 2009 Equity Incentive Plan, zero shares remained available under the 2010 Non-Employee Directors' Stock Award Plan and 53,509 shares remained available under the 2010 Employee Stock Purchase Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item concerning transactions with related persons is incorporated by reference to the 2019 Proxy Statement.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item concerning fees and services of accountants and auditors is incorporated by reference to the 2019 Proxy Statement.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Item 15(a)

(1) Financial Statements

(2) Financial Statement Schedules

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in the financial statements or notes thereto beginning on page F-1 of this report.

(3) Exhibits

The following exhibits are filed with this form 10-K or incorporated herein by reference to the document set forth next to the exhibit listed below. Where so indicated, exhibits that were previously filed are incorporated by reference.

		Incorporated By Reference			
Exhibit Number	Description	Form	Filing Date	Number	Filed Herewith
2.1	Asset Purchase Agreement, dated March 19, 2017, between Bluelink Pharmaceuticals, Inc. and Cerulean Pharma, Inc.	8-K	3/20/2017	2.1	
3.1	Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2	Certificate of Amendment to Restated Certificate of Incorporation filed on May 10, 2013	8-K	5/14/2013	3.1	
3.3	Amended and Restated Bylaws	8-K	11/18/2011	3.2	
4.1	Form of the Registrant's Common Stock Certificate	S-1/A	10/26/2011	4.1	
4.2	Reference is made to Exhibits 3.1, 3.2 and 3.3				
4.3	Amended and Restated Investor Rights Agreement by and between the Registrant and certain holders of the Registrant's capital stock dated as of December 1, 2010	10-Q	5/10/2012	4.3	
10.1†	Form of Indemnity Agreement by and between the Registrant and its directors and executive officers	S-1/A	11/8/2011	10.11	
10.2†	2000 Equity Incentive Plan	S-1	12/21/2010	10.2	
10.3.1†	Form of Stock Option Agreement under 2000 Equity Incentive Plan	S-1	12/21/2010	10.3	
10.3.2†	Form of Stock Option Grant Notice under 2000 Equity Incentive Plan	S-1	12/21/2010	10.4	
10.3.3†	Form of Stock Bonus Agreement under 2000 Equity Incentive Plan	S-1	12/21/2010	10.5	
10.4†	Amended and Restated 2009 Equity Incentive Plan	S-1	12/21/2010	10.6	
10.4.1†	Form of Stock Option Agreement under 2009 Equity Incentive Plan	S-1	12/21/2010	10.7	
10.4.2†	Form of Stock Option Grant Notice under 2009 Equity Incentive Plan	S-1	12/21/2010	10.8	

Exhibit Number	Description	Incorporated By Reference			Filed Herewith
		Form	Filing Date	Number	
10.4.3†	Form of Restricted Stock Unit Award Agreement under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.6	
10.4.4†	Form of Restricted Stock Unit Grant Notice [Four Year Annual Vesting] under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.7	
10.4.5†	Form of Restricted Stock Unit Grant Notice [Immediately Vested] under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.8	
10.5†	2010 Employee Stock Purchase Plan	8-K	5/14/2013	10.2	
10.6†	2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	11/8/2016	10.2	
10.6.1†	Form of Restricted Stock Unit Award Agreement under the 2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	8/5/2014	10.4	
10.6.2†	Form of Restricted Stock Unit Grant Notice under the 2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	8/5/2014	10.5	
10.7*	License Agreement dated September 13, 2005 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.46	
10.7.1*	Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.47	
10.7.2*	Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.48	
10.7.3*	Amendment to License Agreement dated February 13, 2007 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.49	
10.7.4*	Amendment to License Agreement dated March 28, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.3	
10.7.5*	Amendment to License Agreement dated July 10, 2014 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.4	
10.8	Lease dated September 30, 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.53	
10.9	Memorandum of Agreement dated November 14, 2011 by and between NewLink Genetics Corporation and Iowa State University Research Park Corporation	8-K	11/18/2011	10.1	
10.10	Promissory Note executed in 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.54	
10.11	Iowa Values Fund Agreement dated March 18, 2005 by and between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.56	

Exhibit Number	Description	Incorporated By Reference			Filed Herewith
		Form	Filing Date	Number	
10.12	Master Contract dated December 29, 2005 by and between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.58	
10.13	Contract Amendment dated April 21, 2009 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.59	
10.14	Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.57	
10.15	Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.6	
10.16	Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.77	
10.17	Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.78	
10.18	NewLink Genetics Corporation 401(k) Prototype Plan and Trust, effective as of January 1, 2005	8-K	3/12/2012	10.2	
10.19	NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2005	8-K	3/12/2012	10.3	
10.20	Material Modification to the NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2011	8-K	3/12/2012	10.4	
10.21	Settlement Agreement with the Iowa Economic Development Authority, effective as of March 26, 2012	8-K	3/28/2012	10.1	
10.22	Memorandum of Agreement dated April 15, 2013 by and between the Registrant and Iowa State University Research Park Corporation	10-Q	5/8/2013	10.1	
10.23	Memorandum of Agreement; Addendum to the Lease Between ISU Research Park Corporation and the Registrant dated March 1, 2010	10-Q	8/8/2013	10.2	
10.24	License Agreement Amendment, by and between NewLink Genetics Corporation and Georgia Health Sciences University Research Institute, dated as of July 13, 2013	10-Q	11/12/2013	10.2	
10.25*	License and Collaboration Agreement dated November 21, 2014 by and among the Company, BioProtection Systems Corporation and Merck Sharp & Dohme Corp.	10-K	3/16/2015	10.105	
10.25.1*	Amendment to License and Collaboration Agreement dated December 5, 2017 by and among the Company, BioProtection Systems Corporation and Merck Sharp & Dohme Corp.	10-K	3/5/2018	10.48.1	
10.25.2*	Amendment to License and Collaboration Agreement by and between Merck Sharp & Dohme Corp., dated May 10, 2018	10-Q	8/6/2018	10.1	

Exhibit Number	Description	Incorporated By Reference			Filed Herewith
		Form	Filing Date	Number	
10.25.3*	Amendment No. 3 to License and Collaboration Agreement by and between the Registrant and Merck Sharp & Dohme Corp., Dated October 9, 2018	10-Q	11/2/2018	10.1	
10.25.4*	Amendment to License and Collaboration Agreement dated January 14, 2019 by and among the Company, BioProtection Systems Corporation and Merck Sharp & Dohme Corp.				X
10.26	Memorandum of Agreement dated February 12, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010	10-K	3/16/2015	10.108	
10.27*	Sixth Amendment, effective March 15, 2016, to the License Agreement between Augusta University Research, Inc., the Georgia Health Sciences University Research Institute, Inc., and Medical College of Georgia Institute and the Registrant, dated September 13, 2005.	10-Q/A	11/3/2016	10.8	
10.28*	Research Services Agreement, dated March 18, 2016, between the Registrant and Augusta University Research Institute, Inc.	10-Q/A	11/3/2016	10.1	
10.29	Controlled Equity Offering Sales Agreement, dated March 12, 2018, between the Registrant and Cantor Fitzgerald, Co.	8-K	3/13/2018	10.1	
10.30	License Agreement, dated March 19, 2017 between BlueLink Pharmaceuticals, Inc. and Cerulean Pharma, Inc.	8-K	3/20/2017	10.1	
10.31†	Employment Agreement, dated January 4, 2016, by and between the Registrant and Charles J. Link	8-K	1/7/2016	10.3	
10.32†	Employment Agreement, dated January 4, 2016, by and between the Registrant and Dr. Nicholas N. Vahanian	8-K	1/7/2016	10.4	
10.33†	Employment Agreement, dated July 26, 2018, by and between the Registrant and Carl Langren	10-Q	11/2/2018	10.4	
10.34†	Employment Agreement, dated January 4, 2016, by and between the Registrant and John B. Henneman, III	10-K/A	4/9/2018	10.62	
10.35†	Employment Agreement, dated January 4, 2016, by and between the Registrant and Gene Kennedy	10-K/A	4/9/2018	10.63	
10.36†	Employment Agreement, dated July 26, 2018, by and between the Registrant and Lori Lawley	10-Q	11/2/2018	10.5	
10.37†	Separation and Release Agreement, dated as of July 26, 2018, between the Registrant and John B. “Jack” Henneman III	10-Q	11/2/2018	10.2	
10.38†	Employment Agreement, dated January 4, 2016, by and between the Registrant and Brian Wiley	8-K	1/7/2016	10.7	
10.39†	Separation and Release Agreement, dated July 26, 2018, between the Registrant and Brian Wiley	10-Q	11/2/2018	10.3	

Exhibit Number	Description	Incorporated By Reference			Filed Herewith
		Form	Filing Date	Number	
10.40*	Amended and Restated License Agreement by and between BioProtection Systems Corporation and Her Majesty the Queen in Right of Canada, as represented by the Minister of Health, acting through the Public Health Agency of Canada, dated December 5, 2017.	10-K	3/5/2018	10.61	
10.40.1	Amendment to the Amended and Restated License Agreement by and between BioProtection Systems Corporation and Her Majesty the Queen in Right of Canada, as represented by the Minister of Health, acting through the Public Health Agency of Canada, dated December 27, 2018.				X
21.1	Subsidiary Information				X
23.1	Consent of KPMG LLP, independent registered public accounting firm				X
24.1	Power of Attorney (included on signature page hereto)				X
31.1	Rule 13a-14(a)/15d-14(a) Certification				X
31.2	Rule 13a-14(a)/15d-14(a) Certification				X
32.1#	Section 1350 Certification				X
101.INS	XBRL Instance Document (filed electronically herewith)				X
101.SCH	XBRL Taxonomy Extension Schema Document (filed electronically herewith)				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (filed electronically herewith)				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document (filed electronically herewith)				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (filed electronically herewith)				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (filed electronically herewith)				X

† Indicates management contract or compensatory plan.

* Indicates confidential treatment has been requested with respect to specific portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 19434, as amended.

The certifications attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NewLink Genetics Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

NEWLINK GENETICS CORPORATION

By: /s/ Charles J. Link, Jr.
Charles J. Link, Jr.
Chief Executive Officer
(Principal Executive Officer)
Date: March 5, 2019

By: /s/ Carl W. Langren
Carl W. Langren
Chief Financial Officer and Secretary
(Principal Financial Officer)
Date: March 5, 2019

By: /s/ Lori D. Lawley
Lori D. Lawley
Vice President Finance
(Principal Accounting Officer)
Date: March 5, 2019

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Charles J. Link, Jr. and Carl W. Langren, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant and in the capacities indicated:

Name	Title	Date
/s/ Charles J. Link, Jr. Charles J. Link, Jr.	Chief Executive Officer, Chairman of Board of Directors and Director (Principal Executive Officer)	March 5, 2019
/s/ Carl W. Langren Carl W. Langren	Chief Financial Officer and Secretary (Principal Financial Officer)	March 5, 2019
/s/ Lori D. Lawley Lori D. Lawley	Vice President Finance (Principal Accounting Officer)	March 5, 2019
/s/ Thomas A. Raffin Thomas A. Raffin	Director	March 5, 2019
/s/ Ernest J. Talarico, III Ernest J. Talarico, III	Director	March 5, 2019
/s/ Lota Zoth Lota Zoth	Director	March 5, 2019
/s/ Chad A. Johnson, JD Chad A. Johnson, JD	Director	March 5, 2019
/s/ Matthew L. Sherman, MD Matthew L. Sherman, MD	Director	March 5, 2019
/s/ Nicholas N. Vahanian Nicholas N. Vahanian	Director	March 5, 2019

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors

NewLink Genetics Corporation:

Opinions on the Consolidated Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying consolidated balance sheets of NewLink Genetics Corporation and subsidiaries (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, equity, and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes (collectively, the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG LLP

We have served as the Company's auditor since 2002.

Des Moines, Iowa
March 5, 2019

NewLink Genetics Corporation
and Subsidiaries
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 120,738	$ 158,708
Prepaid expenses and other current assets	5,536	6,226
Current income tax receivable	339	356
Other receivables	459	10,176
Total current assets	127,072	175,466
Non-current assets:		

Property and equipment, net	3,727	5,091	
Income tax receivable	140	140	
Total non-current assets	3,867	5,231	
Total assets	$ 130,939	$ 180,697	

Liabilities and Stockholders' Equity

Current liabilities:			
Accounts payable	$ 555	$ 9,256	
Accrued expenses	8,139	12,467	
Current portion of unearned revenue	—	56	
Current portion of deferred rent			

92

92

Current portion of notes payable and obligations under capital leases

61

160

Total current liabilities

8,847

22,031

Long term liabilities:

Royalty obligation payable to Iowa Economic Development Authority

6,000

6,000

Notes payable and obligations under capital leases

43

111

Deferred rent

906

998

Total long-term liabilities

6,949

7,109

Total liabilities

15,796

29,140

Stockholders’ Equity:

Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at December 31, 2018 and 2017; issued and outstanding shares — 0 at December 31, 2018 and 2017

—

—

Common stock, $0.01 par value: Authorized shares — 75,000,000 at December 31, 2018 and 2017; issued 37,343,547 and 37,168,122 at December 31, 2018 and 2017, respectively and outstanding 37,251,220 and 37,109,556 at December 31, 2018 and 2017, respectively

373

372

Additional paid-in capital

407,199

389,786

Treasury stock, at cost: 92,327 and 58,566 shares at December 31, 2018 and 2017

(1,417
)

(1,142
)
Accumulated deficit

(291,012
)

(237,459
)
Total stockholders’ equity

115,143

151,557

Total liabilities and stockholders’ equity
$
130,939

$
180,697

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation
and Subsidiaries
Consolidated Statements of Operations
(In thousands, except share and per share data)

	Year Ended December 31,		
	2018	**2017**	**2016**
Grant revenue	$ 11,268	$ 28,321	$ 32,242
Licensing and collaboration revenue	1,206	390	3,526
Total operating revenues	12,474	28,711	35,768
Operating expenses:			
Research and development	45,694		

69,866

93,300

General and administrative

29,218

31,726

33,226

Total operating expenses

74,912

101,592

126,526

Loss from operations

(62,438
)

(72,881
)

(90,758
)
Other income and expense:

Miscellaneous (expense) income

(102
)

(126
)

32

Interest income

2,029

616

237

Interest expense

(52
)

(119
)

(22
)
Other income, net

1,875

371

247

Loss before taxes

(60,563
)

(72,510
)

(90,511
)
Income tax benefit

6,968

559

5,356

Net loss
$
(53,595
)
$
(71,951
)
$
(85,155
)

Basic and diluted loss per share
$
(1.44
)
$

(2.30
)
$
(2.94
)

Basic and diluted average shares outstanding

37,191,262

31,304,309

28,979,327

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation
and Subsidiaries
Consolidated Statements of Equity
(In thousands, except share and per share data)

Common Stock

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2015	28,814,142	$ 288	$ 276,610	$ (771)	$ (80,353)	$ 195,774
Share-based compensation	—	—	16,707	—	—	16,707
Exercise of stock options and vesting of restricted stock awards	296,933					

4

1,675

—

—

1,679

Sales of shares under stock purchase plan

58.609

—

543

—

—

543

Shares withheld for statutory tax withholding

(6,011
)

—

—

(82
)

—

(82
)
Net loss

—

—

—

—

(85,155)						
(85,155)						
Balance at December 31, 2016	29,163,673	$ 292	$ 295,535	$ (853)	$ (165,508)	$ 129,466
Share-based compensation	—	—	18,508	—	—	18,508
Exercise of stock options and vesting of restricted stock awards	212,961	2	960	—	—	962
Sales of shares under stock purchase plan	70,787					

1

444

—

—

445

Issuance of common stock under the ATM Offering (net of offering costs of $561 thousand)

1,940,656

19

19,314

—

—

19,333

Issuance of common stock under public offering (net of offering costs of $3.7 million)

5,750,000

58

55,025

—

—

55,083

Shares withheld for statutory tax withholding

(28,521
)

—

—

(289
)

—

(289) Net loss						
—						
—						
—						
—						
(71,951)						
(71,951) Balance at December 31, 2017	37,109,556	$ 372	$ 389,786	$ (1,142)	$ (237,459)	$ 151,557
Share-based compensation	—	—	17,120	—	—	17,120
Exercise of stock options and vesting of restricted stock awards	126,938					

1

142

—

—

143

Sales of shares under stock purchase plan

48,487

—

151

—

—

151

Shares withheld for statutory tax withholding

(33,761
)

—

—

(275
)

—

(275
)
Cumulative effect of accounting change

—

—

—

—

42									
Net loss									
—									
—									
—									
—									
(53,595)									
(53,595)									
Balance at December 31, 2018									
37,251,220	$	373	$	407,199	$	(1,417)	$	(291,012)	$	115,143

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation
and Subsidiaries
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2018	**2017**	**2016**
Cash Flows From Operating Activities			
Net loss	$ (53,595)	$ (71,951)	$ (85,155)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	17,120	18,508	16,707
Depreciation and amortization	1,145	1,407	2,084
Forgiveness of debt	—	—	

(397
)
Impairment of fixed assets

—

—

3,958

Loss on sale of fixed assets

102

126

—

Changes in operating assets and liabilities:

Prepaid expenses and other assets

226

(305
)

(965
)
Other receivables

10,223

14,350

(19,139
)
Accounts payable and accrued expenses

(13,029
)

(15,469
)

24,770

Income taxes payable (receivable)

17

5,479

(6,834
)
Unearned revenue

(56
)

(335
)

(68
)
Deferred rent

(92
)

(91
)

(908
)
Net cash used in operating activities

(37,939
)

(48,281
)

(65,947
)
Cash Flows From Investing Activities

Maturity of certificates of deposit

—

—

2,180

Purchase of equipment

(7
)

(43
)

(2,246
)

Proceeds on sale of fixed assets

124

254

—

Net cash provided by (used in) investing activities

117

211

(66
)

Cash Flows From Financing Activities

Issuance of common stock, net of offering costs

—

74,416

—

Issuance of common stock under share-based compensation plans

294

1,407

2,222

Repurchase of common stock

(275
)

(289
)

(82
)

Payments under capital lease obligations and principal payments on notes payable

(167
)

(246

)

(257
)
Net cash (used in) provided by financing activities

(148
)

75,288

1,883

Net (decrease) increase in cash and cash equivalents

(37,970
)

27,218

(64,130
)
Cash and cash equivalents at beginning of year

158,708

131,490

195,620

Cash and cash equivalents at end of year
$
120,738

$
158,708

$
131,490

Supplemental disclosure of cash flows information:

Cash paid for interest
$
8

$
15

$
22

Cash paid for taxes	25	643	1,022
Proceeds from income tax refunds	7,057	6,651	197
Noncash financing and investing activities:			
Assets acquired under capital lease	$ —	$ —	$ 231

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

1. Description of Business Activities

NewLink Genetics Corporation (NewLink) was incorporated as a Delaware corporation on June 4, 1999 and initiated operations in April of 2000.

NewLink and its subsidiaries (the Company) are devoting substantially all of their efforts toward research and development. The Company has incurred significant losses in all years since being incorporated, except for the year ended December 31, 2014, and has never generated revenue from commercial sales of its drugs.

The accompanying financial statements as of and for the year ended December 31, 2018 have been prepared assuming the Company will continue as a going concern. The Company raised net proceeds of $37.6 million from its IPO, completed a follow-on offering of its common stock raising net proceeds of $49.0 million, and raised an additional $58.7 million in net proceeds from an at the market offering prior to March 31, 2015.

During 2017, the Company sold 1,940,656 shares of its common stock under an ATM offering, with aggregate net proceeds of $19.3 million after commissions of $398,000 paid to Cantor Fitzgerald & Co. (Cantor) as the placement agent, and other costs of $163,000. In October 2017, the Company sold 5,750,000 of its shares of common stock in a public offering for aggregate net proceeds of $55.2 million after underwriters' discounts, commissions and other expenses of $3.7 million.

The Company's cash and cash equivalents are expected to be adequate to satisfy the Company's liquidity requirements through 2021. If available liquidity becomes insufficient to meet the Company's operating obligations as they come due, the Company's plans include pursuing alternative funding arrangements and/or reducing expenditures as necessary to meet the Company's cash requirements. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity. Failure by the Company to successfully execute its plans or otherwise address its liquidity needs may have a material adverse effect on its business and financial position, and may materially affect the Company's ability to continue as a going concern.

2. Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles, or U.S. GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the financial statements of NewLink and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents

For the purposes of the consolidated statements of cash flows, the Company considers all highly liquid debt instruments with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents of $120.7 million and $158.7 million at December 31, 2018 and 2017, respectively, consist of checking accounts, money market accounts and treasury bills.

Leasehold Improvements and Equipment, and Deferred Rent

Leasehold improvements and equipment are capitalized as the Company believes they have alternative future uses and are stated at cost. Equipment under capital leases is stated at the present value of future minimum lease payments. Depreciation on all leasehold improvements and equipment is calculated on the straight-line method over the shorter of the lease term or estimated useful life of the asset. Computer equipment has useful lives of three to five years, lab equipment has a useful life of five years and contract manufacturing organization equipment has a useful life of five years.

Deferred rent reflects improvement allowances from the Company's lessors deferred to be recognized as part of lease expense over the remaining term of the lease, which is recognized on a straight-line basis. Total deferred rents were $998,000 and $1.1 million as of December 31, 2018 and 2017, respectively.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future net undiscounted cash flows expected to be generated by the asset group, primarily relating to proceeds for selling the assets. If such assets are considered to be impaired, the impairment to be recognized is measured at the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

Revenue Recognition

Revenues are recognized under Topic 606 when control of the promised goods or services is transferred to the Company's customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. The Company receives payments from government entities under its grants and contracts with the Department of Defense and the United States Department of Health and Human Services, or HHS. These agreements provide the Company cost reimbursement plus a percentage for certain types of expenditures in return for research and development activities over a contractually defined period. Grant revenues are recognized over time and measured using the input method. The Company uses labor costs and subcontractor fees as inputs to measure progress towards satisfying its performance obligations under these agreements. This is the most faithful depiction of the transfer of goods and services to the government entities due to the government entities' control over the research and development activities. Under this method, the Company recognizes revenue generally in the period during which the related costs are incurred, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services.

During the years ended December 31, 2018, 2017, and 2016, the Company has earned $11.3 million, $28.3 million, and $32.2 million in grant revenue, respectively. The Company had $309,000 and $9.3 million of receivables from the government contracts recorded in other receivables and $0 and $465,000 of unbilled expenses relating to the government contracts recorded in prepaid expenses and other assets on the balance sheet as of December 31, 2018 and 2017, respectively. The Company had $54,000 and $1.8 million of accrued expenses for subcontractor fees and $161,000 and $4.9 million of subcontractor fees in accounts payable for amounts incurred under the government contracts as of December 31, 2018 and 2017, respectively.

Expenses Accrued Under Contractual Arrangements with Third Parties; Accrued Clinical Expenses

The Company estimates its accrued expenses through a process of reviewing open contracts and purchase orders, communicating with personnel to identify services that have been performed and estimating the level of service performed and the associated cost incurred for the service that may not be invoiced from the provider. The estimates of accrued expenses as of each balance sheet date are based on facts and circumstances known at that time. Such estimates are periodically confirmed with the service providers to verify accuracy.

The Company bases its expenses related to clinical trials on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on behalf of the Company. Invoicing from third-party contractors for services performed can lag several months. The Company accrues the costs of services rendered in connection with third-party contractor activities based on its estimate of management fees, site management and monitoring costs and data management costs as contracted. Differences between actual clinical trial costs and estimated clinical trial costs are adjusted for in the period in which they become known through operations.

Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist primarily of employee-related expenses, which include salaries, bonuses, benefits and share-based compensation;

manufacturing-related costs; clinical trial expenses which include expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials; facilities, depreciation of fixed assets and other allocated expenses, which include direct and allocated expenses for rent and maintenance of research facilities and equipment; license fees for and milestone payments related to in-licensed products and technology; and costs associated with non-clinical activities and regulatory approvals.

Patents

The Company generally applies for patent protection on processes and products. Patent application costs are expensed as incurred as a component of general and administrative expense, as recoverability of such expenditures is uncertain.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operating results in the period that includes the enactment date. Management assesses the realizability of deferred tax assets and records a valuation allowance if it is more likely than not that all or a portion of the deferred tax assets will not be realized.

The Company accounts for the effect of any uncertain tax positions based on a more likely than not threshold to the recognition of the tax positions being sustained based on the technical merits of the position under scrutiny by the applicable taxing authority. If a tax position or positions are deemed to result in uncertainties of those positions, the unrecognized tax position is estimated based on a cumulative probability assessment that aggregates the estimated tax liability for all uncertain tax positions. Interest and penalties assessed, if any, are recorded in its consolidated statement of operations in interest expense and other expenses. As of December 31, 2018 and 2017, the Company had a recognized uncertain tax position of $653,000.

Share-Based Compensation

The Company is required to estimate the grant-date fair value of share-based payment transactions with employees which include stock options, restricted stock units (RSUs) and performance shares (PSUs) and recognizes the compensation cost over the requisite service period based on the estimated fair values as well as expected forfeiture rates. The Company estimates the fair value of each award granted using the Black-Scholes option pricing model. The Black-Scholes model requires the input of assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs. The Company calculates the fair value of the award on the grant date, which is the date the award is authorized by the Board of Directors or Chief Executive Officer and the employee has an understanding of the terms of the award.

Generally, the Company has issued employee awards that vest either monthly or 25% vest on the first anniversary date of issuance with the remaining options vesting ratably over the next 36 months. The Company records compensation cost on a straight-line basis over the vesting period. The fair value of RSUs that are subject to cliff vesting are recognized as compensation expense over the requisite service period using the straight line attribution method, and the fair value of RSUs that are subject to graded vesting are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of PSUs are recognized as compensation expense beginning at the time in which the performance conditions are deemed probable of achievement, over the remaining requisite service period.

The Company has issued awards to nonemployee consultants and advisers. All grants to nonemployees are valued using the same fair value method that we use for grants to employees. The compensation cost on these awards is measured each period until vesting, and is recognized through the earlier of the vesting of the award or completion of services by the nonemployee.

Following is a description of the inputs for the Black-Scholes model:

Exercise Price

The Company uses the quoted market price as listed on the public exchange on the date of grant. If Incentive Stock Options are granted to a 10% stockholder in the Company, the exercise price shall not be less than 110% of the common stock's fair market value on the date of grant.

Expected Term (in Years)

The expected term of a stock option is the period of time for which the option is expected to be outstanding. The Company uses historical exercise and option expiration data to estimate the expected term for the Black-Scholes grant-date valuation.

Risk-Free Interest Rate

The Company uses the average yield on current U.S. Treasury instruments with terms that approximate the expected term of the stock options being valued.

Expected Dividend Yield

The expected dividend yield for all of the Company's stock option grants is 0%, as the Company has not declared a cash dividend since inception and has no plans to declare a dividend.

Expected Volatility

The Company uses its historical stock price volatility. The volatility is calculated over a period of time commensurate with the expected term for the options granted.

Forfeitures

The share-based compensation expense has been reduced for estimated forfeitures. The estimated forfeiture rate is based on historical experience of the Company's option plan, which the Company expects to continue at the current level, and any adjustments in the forfeiture rate in the future will result in a cumulative adjustment in the period that this estimate is changed. Ultimately, the total compensation expense recognized for any given stock-based award over its vesting period will only be for those shares that actually vest.

Segments

The Company operates in one segment. The Company conducts research and development activities based from facilities located in Ames, Iowa and has corporate headquarters in Ames, Iowa and Austin, Texas. The Company conducts preclinical and clinical research in the biopharmaceutical industry. The chief operating decision maker uses cash flow as the primary measure to manage the business and management does not segment its business for internal reporting or decision-making.

Financial Instruments and Concentrations of Credit Risk

The fair values of cash and cash equivalents, receivables and accounts payable, which are recorded at cost, approximate fair value based on the short-term nature of these financial instruments. The fair value of notes payable and capital lease obligations was $104,000 and $271,000 as of December 31, 2018 and 2017, respectively, and was determined using Level 2 inputs (computed in accordance with ASC 820). The Company is unable to estimate the fair value of the royalty obligation based on future product sales as the timing of payments, if any, is uncertain.

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, the Company's cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, the Company invests its excess cash primarily in high quality securities such as money market funds.

Earnings per share (EPS)

The Company computes basic EPS attributable to the Company's common stockholders by dividing net income (loss) attributable to the Company by our weighted-average common shares outstanding during the period. Diluted EPS reflects the potential dilution beyond shares for basic EPS that could occur if securities or other contracts to issue common stock were exercised, converted into common stock, or resulted in the issuance of common stock that would have shared in our earnings. The Company computes basic and diluted EPS using net income (loss) attributable to the Company's common stockholders, and its actual weighted-average shares.

Concentration of Revenue

Genentech, a member of the Roche Group, and Merck Sharpe and Dohme Corp., or Merck, accounted for 0.4% and 9.2%, respectively, of the $12.5 million of revenue for the year ended December 31, 2018, with the remainder obtained from government grants. Genentech and Merck accounted for 1.2% and 0.2%, respectively, of the $28.7 million of revenue earned for the year ended December 31, 2017, with the remainder obtained from government grants. Genentech and Merck accounted for 7.6% and 2.3%, respectively, of the $35.8 million of revenue earned for the year ended December 31, 2016, with the remainder obtained from government grants.

Recently Adopted Accounting Pronouncements

On May 28, 2014, the FASB issued ASU No. 2014-09 (Topic 606), Revenue from Contracts with Customers. Topic 606 supersedes the revenue recognition requirements in Topic 605 "Revenue Recognition" (Topic 605), and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted Topic 606 as of January 1, 2018, and as a result, changed its accounting policy for revenue recognition, as discussed in Note 3.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02 (Topic 842), Leases, to improve financial reporting for leasing transactions. The Company will adopt the standard on January 1, 2019 using the modified retrospective method, as required, applying the new standard to all leases existing as of the date of initial application. The Company has elected that the date of initial application will be the effective date, or January 1, 2019. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. The new standard provides a number of optional practical expedients in transition. The Company expects to elect the 'package of practical expedients', which permits the Company not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company does not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to the Company.

The Company expects that this standard will have a material effect on its consolidated balance sheet due to the recognition of right-of-use assets and lease liabilities. While the Company continues to assess all of the effects of adoption, the Company expects it to primarily relate to the operating leases for office and laboratory space noted in "Part I. Item 2. Properties" of this Annual Report on Form 10-K, for which the Company will record a lease liability and corresponding right-of-use asset upon adoption. The lease liability will equal the present value of unpaid minimum lease payments for operating leases that exist as of the date of initial application of the new standard. Future undiscounted obligations related to facility leases in effect as of the date of initial application of the new standard are included in the table of future minimum lease payments disclosed in Note 4, and aggregate to $11.4 million.

3. Revenues

Adoption of ASC Topic 606, "Revenue from Contracts with Customers"

On January 1, 2018, we adopted Topic 606 using the modified retrospective method by recognizing the cumulative effect of initially applying Topic 606 as an adjustment to the opening balance of equity as of January 1, 2018. Therefore results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while

prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting policy under Topic 605. The change in accounting policy from Topic 605 to Topic 606 impacted how the Company recognizes revenue from government grants and collaboration revenues, however, it did not impact the accounting for our historical license and collaboration agreements, due to the nature of those services in the period leading up to the adoption of Topic 606.

The Company recorded an immaterial net reduction to the opening accumulated deficit within equity as of January 1, 2018 due to the cumulative impact of adopting Topic 606 with respect to grants from government entities which were not completed as of the date of adoption. As a result of applying the modified retrospective method to adopt the new revenue guidance, the following adjustments were made to accounts on the Consolidated Balance Sheet as of January 1, 2018 (in thousands):

Balance Sheet

	As Reported December 31, 2017	Adjustments	Adjusted January 1, 2018
Assets:			
Prepaid expenses and other current assets	$ 6,226	$ (464)	$ 5,762
Other receivables	$ 10,176	$ 506	$ 10,682
Total Assets	$ 180,697	$ 42	$ 180,739
Equity:			

Accumulated deficit
$
(237,459
)
$
42

$
(237,417
)
Total liabilities and stockholders’ equity
$
180,697

$
42

$
180,739

The impact of adoption on the Company’s Consolidated Statement of Operations for the year ending December 31, 2018 was as follows (in thousands):

	Year Ended December 31, 2018		
Statement of Operations	**As Reported**	**Adjustments**	**Balance without Adoption of Topic 606**
Grant Revenues	$ 11,268	$ 346	$ 11,614
Licensing and collaboration revenue	$ 1,206	$ 116	$ 1,322
Research and Development	$ 45,694	$ 420	$ 46,114
Net Loss	$ (53,595)	$ 42	$ (53,553)

The impact of adoption on the Company’s Consolidated Statement of Cash Flows for the year ending December 31, 2018 was as follows (in thousands):

	Year Ended December 31, 2018		
Statement of Cash Flows	**As Reported**	**Adjustments**	**Balance without Adoption of Topic 606**
Net Loss	(53,595)	42	(53,553)
Changes in operating assets and liabilities			
Other receivables	10,223	(492)	9,731
Accounts payable and accrued expenses	(13,029)	450	(12,579)
Net cash used in operating activities	(37,939)	—	(37,939)

NewLink Genetics Corporation
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Notes to Consolidated Financial Statements

4. Leases

(a) Capital Leases

The following is an analysis of the leased property under capital leases by major class (in thousands):

	Asset Balances at December 31,	
Class of property	**2018**	**2017**
Lab equipment	$ 720	$ 720
Leasehold improvements	27	27
Computer equipment	54	54
Total property under capital leases	801	801
Less accumulated depreciation and amortization	(703)	(652)
Capital leased assets, net	$ 98	$ 149

The depreciation and amortization reflected above has been recorded in both research and development and general administrative expense in the consolidated statements of operations.

We have no future minimum lease payments under capital leases as of December 31, 2018.

(b) Operating Leases

The Company has certain facility leases with non-cancellable terms ranging between one and three years, with certain renewal options. Lease expense is recognized on a straight-line basis. Rental expense for operating leases during the years ended December 31, 2018, 2017 and 2016, was $1.1 million, $1.2 million, and $1.7 million, respectively, including those with terms less than one year, and has been included in both research and development and general and administration in the consolidated statements of operations.

Future minimum lease payments under the noncancelable operating leases (with initial or remaining lease terms in excess of one year), with certain renewal options, as of December 31, 2018 are as follows (in thousands):

Year Ending December 31:	
2019	$ 1,105
2020	1,004
2021	923
2022	906
2023	909
Thereafter	6,570
Total	$ 11,417

5. Leasehold Improvements and Equipment

Leasehold improvements and equipment at December 31, 2018 and 2017 consisted of the following:

	Year Ended December 31,	
	2018	2017
Leasehold improvements	$ 5,300	$ 5,310
Computer and office equipment	1,984	2,326
Lab and leased equipment	3,398	3,979
Contract manufacturing organization equipment	30	114
Assets not placed in service	—	—
Total leasehold improvements and equipment	10,712	11,729
Less accumulated depreciation and amortization	(6,985)	(6,638)
Total leasehold improvements and equipment, net	$ 3,727	$ 5,091

6. Long-Term Debt and Conversion to Royalty Obligation

March 2005 Iowa Department of Economic Development Loan

In March 2005, the Company entered into a $6.0 million forgivable loan agreement with the Iowa Department of Economic Development, or the IDED. Under the agreement, in the absence of default, there were no principal or interest payments due until the completion date for the project. The balance outstanding under the loan agreement was $6.0 million as of December 31, 2011. This loan was converted into a royalty obligation under the terms of a settlement agreement entered into on March 26, 2012, or the IEDA Agreement, with the Iowa Economic Development Authority (the IEDA), as successor in interest to the IDED.

March 2012 IEDA Royalty Obligation

Under the terms of the IEDA Agreement the Company agreed to pay a 0.5% royalty on future product sales up to a cap of $6.8 million in exchange for IDED's release of the Company's job creation and project expenditure obligations and their release of the security interest in substantially all of the Company's assets. As no payments are expected in the next 12 months, the entire accrued royalty obligation of $6.0 million is considered long-term as of December 31, 2018.

2009 and 2012 Iowa State University Research Park Notes

In 2009, the Company executed a promissory note in favor of Iowa State University Research Park, or ISURP, in an original principal amount of $800,000, which is due in monthly installments through March, 2018. The note represents amounts owed by the Company to ISURP for certain improvements that were made to facilities the Company leases from ISURP. The principal and interest owed under the note is amortized over an eight-year period. Interest is payable monthly under this promissory note, initially at a rate of 3.0% per annum and increasing to 5.0% per annum after five years from the date the improvements were completed. ISURP may accelerate all amounts owed under the note upon an event of default, including the Company's uncured material breach of the terms of the note or the lease or upon early termination of the lease. In the event of a default under the note, amounts owed under the note will bear interest at 8.0% per annum. The balance outstanding under the 2009 note was $0 and $29,000 at December 31, 2018 and December 31, 2017, respectively.

In 2012, the Company executed a promissory note in favor of ISURP in an original principal amount of $456,000, which is due in monthly installments through September 2020. The note represents amounts owed by the Company to ISURP for certain additional improvements that were made to facilities the Company leases from ISURP. The principal and interest owed under the note is amortized over an eight-year period. Interest is payable monthly under this promissory note, initially at a rate of 3.0% per annum and increasing to 5.0% per annum after five years from the date the improvements were completed. ISURP may accelerate all amounts owed under the note upon an event of default, including the Company's uncured material breach of the terms of the note or the lease or upon early termination of the lease. In the event of a default under the note, amounts owed under the note will bear interest at 8.0% per annum. The balance outstanding under the 2012 note was $111,000 and $169,000 at December 31, 2018 and December 31, 2017, respectively.

March 2010 City of Ames Forgivable Loan

In March 2010, the Company entered into a $400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, jointly, as lenders. The project provided the Company with financial assistance to construct new facilities within the Ames city limits. In the absence of a default, there were no principal or interest payments due until March 10, 2016.

The project called for the Company to create or retain at least 150 full-time positions located in Ames, Iowa by March 10, 2016. The agreement required the Company to enter into a five-year building lease with the option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015, which requirement the Company met by the March 10, 2015 deadline. As of March 10, 2016, the Company had satisfactorily fulfilled all of the above terms of the loan agreement and the loan was forgiven. Accordingly, the entire amount of $397,000 was derecognized with a corresponding amount recorded in grant revenue for the year ended December 31, 2016.

7. License and Research Collaboration Agreements

Genentech, a Member of the Roche Group

In October 2014, the Company entered into a worldwide exclusive collaboration and license agreements with Genentech for the development and commercialization of NLG919, one of NewLink's clinical stage IDO pathway inhibitors and for a research collaboration for the discovery of next generation IDO/TDO compounds to be developed and commercialized under this agreement. Under the terms of the agreement, the Company received a nonrefundable upfront cash payment of $150.0 million from Genentech in 2014. On June 6, 2017, we received a formal notice of Genentech's intent to terminate the Genentech Agreement with respect to NLG919. As part of the partial termination, worldwide rights to NLG919 reverted to us, and Genentech granted to us an exclusive, royalty-bearing license under certain Genentech intellectual property to develop and commercialize NLG919. If NLG919 is commercialized, we will be obligated to pay to Genentech royalties as a low single-digit percentage of net sales of NLG919.

Additionally, on May 9, 2018 the Company received formal notice that Genentech would not continue the collaboration with respect to next generation IDO/TDO inhibitors identified through the research program. The Genentech Agreement terminated in its entirety on November 6, 2018.

The Company was obligated to deliver multiple non-contingent deliverables related to the NLG919 upfront cash payment. These deliverables include the NLG919 development and commercialization license, research license, program materials and technology, clinical supply of NLG919 product, manufacturing technology, participation in a joint research committee, or JRC, and providing an alliance manager. The Company's obligations under the JRC ended November 2016. The NLG919 development and commercialization license and research license are separate deliverables, but without the ability to develop NLG919, the ability to perform research on the compound would not benefit Genentech. Therefore, the Company believes that the value of the development and commercialization license cannot be separated from the research license value and the two are valued together. The other deliverables qualify as separate units of accounting.

The respective standalone value from each of these deliverables was determined by applying the best estimated selling price method and the revenue was allocated based on the relative selling price method with revenue recognition timing to be determined either by delivery or the provision of service. The estimated selling price determination required the use of significant estimates. To determine the stand-alone value of the license, we considered the negotiation discussions that led to the final terms of the agreement. The Company utilized historical cost plus an estimated gross margin to estimate the selling price for program materials and technology, manufacturing technology, clinical supply, participation in a JRC, and participation of an alliance manager. The program materials and technology, clinical supply of NLG919, participation in a JRC and participation of an alliance manager were delivered throughout the duration of the agreement. The license and manufacturing technology was delivered shortly after the effective date of the agreement.

The Company recognized revenue under this agreement of $56,000 for the year ended December 31, 2018. This amount includes the recognition of $56,000 for providing an alliance manager to the collaboration. All deliverables identified within the collaboration and license agreement have been completed in their entirety and there is no deferred revenue as of December 31, 2018.

The Company recognized revenue under this agreement of $335,000 for the year ended December 31, 2017. This amount includes the recognition of $335,000 for providing an alliance manager to the collaboration. Revenue of $56,000 was deferred as of December 31, 2017 for deliverables identified within the collaboration and license agreement that had not yet been completed in their entirety.

The Company recognized revenue under this agreement of $2.7 million for the year ended December 31, 2016. This amount includes the recognition of $180,000 for participation in the JRC, and $670,000 for providing an alliance manager to the collaboration. Additionally, $1.9 million was recognized for amounts received as reimbursement for the Company's employees working on the project. Revenues of $391,000 remain deferred as of December 31, 2016 for deliverables identified within the collaboration and license agreement that have not yet been completed in their entirety.

Merck Sharpe & Dohme Corp.

In November 2014, the Company entered into a licensing and collaboration agreement with Merck to develop, manufacture and commercialize rVSVΔG-ZEBOV GP, an Ebola vaccine the Company licensed from the Public Health Agency of Canada, or PHAC. Under the terms of the agreement, the Company granted Merck an exclusive, royalty-bearing license to the rVSVΔG-ZEBOV GP and related technology. NewLink received a $30.0 million non-refundable, upfront payment in December 2014, and was also eligible for a one-time $20.0 million non-refundable milestone payment upon the initiation of the pivotal clinical trial using the current rVSVΔG-ZEBOV GP vaccine product as one arm of the trial. In February 2015, this milestone was achieved and the Company received the milestone payment. On December 5, 2017, the Merck Agreement was amended in connection with our entry into an Amended and Restated PHAC license on December 5, 2017

NewLink can receive escalating royalties on potential commercial sales by Merck of the current product candidate ranging from single-digit to double-digits on the rVSVΔG-ZEBOV GP license agreement product sales on increasing levels of annual net sales worldwide. Merck will lead the development of rVSVΔG-ZEBOV GP in order to create a marketable product safe for human use.

The Company completed all deliverables under the Merck Agreement in their entirety during the year ended December 31, 2016. The Company recognized revenue under this agreement of $815,300 for the year ended December 31, 2016. This amount includes the recognition of $53,800 relating to the remaining deliverables and $761,500 for the reimbursement of costs associated with the Ebola clinical trials not reimbursed under the Company’s government contracts.

The Company is eligible to receive from Merck tiered royalty payments based on product sales, with royalty rates varying based on Merck sales of the current rVSVΔG-ZEBOV GP vaccine product and Merck sales of other products included within the Company’s patent rights. Royalties will be recognized when Merck results are reported and will be computed in accordance with contract terms.

8. Stockholders’ Equity

Common Stock

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the Company stockholders. Subject to preferences applicable to outstanding preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the Company’s Board of Directors.

In the event of liquidation, dissolution, or winding up of the Company, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities subject to prior distribution rights of the preferred stock.

Preferred Stock

As of December 31, 2018 and 2017, the Company had no outstanding preferred stock. The Company’s Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the voting power and such designations, preferences, and rights of such series, subject to approval of outstanding preferred series shareholders.

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9. Common Stock Equity Incentive Plans

In April 2000, the stockholders approved NewLink's 2000 Equity Incentive Plan. as amended, or the 2000 Plan, and in July 2009, the stockholders approved NewLink's 2009 Equity Incentive Plan, as amended, or the 2009 Plan. Following the approval of the 2009 Plan, all options outstanding under the 2000 Plan were effectively included under the 2009 Plan. Under the provisions of the 2009 Plan, NewLink may grant the following types of common stock awards:

- Incentive Stock Options
- Nonstatutory Stock Options
- Restricted Stock Awards
- Stock Appreciation Rights

Awards under the 2009 Plan, as amended, may be made to officers, employees, members of the NewLink Board of Directors, advisors, and consultants to NewLink. As of December 31, 2018 there were 11,722,602 shares of common stock authorized for the 2009 Plan and 1,879,686 shares remained available for issuance. As of December 31, 2017 there were 10,238,220 shares of common stock authorized for issuance pursuant to the 2009 Plan and 1,195,358 shares remained available for issuance.

The following table summarizes the authorized increases of common stock under the 2009 Plan:

Date Authorized	Authorized Shares Added
May 15, 2010	1,238,095
January 7, 2011	714,286
January 1, 2013	838,375
January 1, 2014	1,066,340
January 1, 2015	1,119,255
January 1, 2016	1,152,565
January 1, 2017	1,166,546
January 1, 2018	1,484,382

Subsequent to year end, on January 1, 2019, an additional 1,490,048 shares of common stock were added to the shares reserved for future issuance under the 2009 plan. The increases in the authorized shares of common stock under the 2009 Plan in 2010 and 2011 were approved by the Company's stockholders. The increases in the authorized shares of common stock under the 2009 Plan in 2012 through 2018 were made pursuant to an "evergreen provision," in accordance with which, on January 1 of each year, from 2012 to (and including) 2019, a number of shares of common stock in an amount equal to 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or such lesser amount of shares (or no shares) approved by the Company's Board of Directors, was added or will be added to the shares reserved under the 2009 Plan.

Under the terms of the Company's 2010 Non-Employee Directors' Stock Option Plan, as amended, or the Directors' Plan, which became effective on November 10, 2011, 238,095 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 161,905 shares of common stock were added to the reserve. As of December 31, 2018, no shares are available for issuance under the Directors' Plan.

Under the terms of the Company's 2010 Employee Stock Purchase Plan, as amended, or the 2010 Purchase Plan, which became effective on November 10, 2011, 214,285 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 185,715 shares of common stock were added to the reserve. As of December 31, 2018, 53,509 shares remained available for issuance under the plan. During the years ended December 31, 2018 and 2017, 48,487 and 70,787 shares of common stock, respectively, were purchased under the terms of the 2010 Purchase Plan.

NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

Share-based Compensation

Share-based employee compensation expense for the years ended December 31, 2018, 2017 and 2016, was $17.1 million, $18.5 million, and $16.7 million, respectively, and is allocated between research and development and general and administrative expenses within the consolidated statements of operations. As of December 31, 2018, the total compensation cost related to unvested option awards not yet recognized was $8.3 million and the weighted average period over which it is expected to be recognized was 2.1 years. The Company recognized no income tax benefit in the consolidated statements of operations for stock-based compensation arrangements for the years ended December 31, 2018, 2017 and 2016, respectively.

Stock Options

The Company's Board of Directors determines the vesting period for each stock option award. Generally, stock options awarded to date under the 2009 Plan vest monthly or vest 25% on the first anniversary date of issuance with the remaining options vesting ratably over the next 36 months. The stock options may include provisions for early exercise of options. If any shares acquired are unvested, they are subject to repurchase at the Company's discretion until they become vested.

The following table summarizes the stock option activity for the year ended December 31, 2018:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	7,206,884	$ 13.73	
Options granted	1,657,523	6.85	
Options exercised	(38,074)	3.78	
Options forfeited	(459,062)	12.39	

Options expired

(387,627
)

25.30

Outstanding at end of period

7,979,644

11.86

4.5

Options exercisable at end of period

6,262,449

$
12.56

3.3

Based on the December 31, 2018 price of $1.52 per share, the intrinsic value of stock options outstanding at December 31, 2018, was $2,357, all of which related to stock options that were vested at that date.

The following table summarizes options that were granted during the years ended December 31, 2018, 2017 and 2016, and the range of assumptions used to estimate the fair value of those stock options using a Black-Scholes valuation model:

	Years Ended December 31,		
	2018	2017	2016
Number of options granted	1,657,523	1,526,787	1,346,758
Risk-free interest rate	2.61%-3.02%	1.91%-2.22%	1.19%-1.97%
Expected dividend yield	—	—	—
Expected volatility	76.2%-79.3%	68.9%-76.9%	67.1%-69.8%
Expected term (in years)	4.0-7.9	1.2-7.8	5.9-7.4
Weighted average grant-date fair value per share	$4.84	$7.72	$11.91

NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

The following table summarizes the intrinsic value of options exercised and the fair value of awards vested during the years ended December 31, 2018, 2017 and 2016:

	Years Ended December 31,		
	2018	2017	2016
Intrinsic value of options exercised	$83,000	$1.0 million	$1.1 million
Fair value of awards vested	$13.0 million	$15.0 million	$15.1 million

Restricted Stock

Restricted stock is common stock that is subject to restrictions, including risks of forfeiture, determined by the plan committee of the Board of Directors in its sole discretion, for so long as such common stock remains subject to any such restrictions. A holder of restricted stock has all rights of a stockholder with respect to such stock, including the right to vote and to receive dividends thereon, except as otherwise provided in the award agreement relating to such award. Restricted stock awards are equity classified within the consolidated balance sheets. The fair value of each restricted stock grant is estimated on the date of grant using the closing price of the Company's Common Stock on The NASDAQ Global Market on the date of grant.

During the year ended December 31, 2018 and 2017, there were no shares of restricted stock granted. Compensation expense is determined for the issuance of restricted stock by amortizing using either a straight-line basis or the accelerated attribution method over the requisite service period, or the vesting period, the aggregate fair value of the restricted stock awarded based on the closing price of the Company's common stock on the date of grant.

A summary of the Company's unvested restricted stock at December 31, 2018 and changes during the year ended December 31, 2018 is as follows:

Restricted Stock		Weighted Average Grant Date Fair Value
Unvested at beginning of period	168,221	$ 35.82
Granted	—	—
Vested	(88,864)	33.98
Forfeited/cancelled	(10,772)	38.63
Unvested at end of period	68,585	$ 37.75

As of December 31, 2018, the total remaining unrecognized compensation cost related to issuances of restricted stock was approximately $1.0 million and is expected to be recognized over a weighted-average period of 0.9 years. The fair value of restricted stock awards vested during the year ended

December 31, 2018 was $673,508.

The Company does not have a formal policy regarding the source of shares issued upon exercise of stock options or issuance of restricted stock. The Company expects shares issued to be issued from treasury shares or new shares.

10. Income Taxes

U.S. Tax Reform

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code that affect fiscal 2017 and 2018. The Tax Act also makes a number of changes to U.S. federal income tax laws that affect 2018 and later years, including, but not limited to, a reduction of the U.S. federal corporate income tax rate from 35% to 21%, the repeal of the corporate alternative minimum tax ("AMT"), the limitation on net operating loss deductions to 80 percent of taxable income for losses beginning after December 31, 2017 and the repeal of the current two-year carryback provision for net operating losses arising after 2017.

In connection with its analysis of the impact of the Tax Act, the Company recorded a net tax benefit of $140,000 in 2017 which is for the release of the valuation allowance that had previously been recorded to offset the

AMT deferred income tax benefit and classified this amount as a noncurrent income tax receivable. The Tax Act provides that AMT credit carryovers are partially refundable beginning in 2018 as an offset to a tax liability. The Company expects the amount to be fully refunded by 2021. The Tax Act had no other material impacts to the consolidated financial statements upon enactment.

Income tax benefit (expense) consists of (in thousands):

Year Ended December 31, 2018:	Current	Deferred	Total
U.S. federal	$ —	$ —	$ —
State and local	6,968	—	6,968
	$ 6,968	$ —	$ 6,968
Year Ended December 31, 2017:			
U.S. federal	$ 332	$ 140	$ 472
State and local	87	—	87
	$ 419	$ 140	$ 559
Year Ended December 31, 2016:			
U.S. federal	$ 6,469	$ —	$ 6,469
State and local	(1,113)	—	(1,113)
	$ 5,356	$ —	$ 5,356

The tax effects of temporary differences that give rise to significant portions of deferred tax assets and the deferred tax liability at December 31, 2018 and 2017 are presented below (in thousands):

	Year Ended December 31, 2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 18,165	$ 10,622
Federal research and development tax credits	28,283	26,327
Share-based compensation	14,150	11,780
Deferred rent	300	327
Accrued compensation	680	789
Unearned revenue	—	17
Charitable contributions	15	39
Leasehold improvements and equipment	417	297

Gross deferred tax assets	62,010	50,198
Less valuation allowance	(62,010)	(50,198)
Total deferred tax assets	—	—

The valuation allowance for deferred tax assets as of December 31, 2018 and 2017 was $62.0 million and $50.2 million, respectively. The net change in the total valuation allowance for the years ended December 31, 2018 and 2017 was an increase of $11.8 million and of $15.1 million, respectively. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of December 31, 2018 and 2017, due to the uncertainty of future recoverability.

NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

Federal operating loss carryforwards as of December 31, 2018 of approximately $74.5 million and federal research credit carryforwards of approximately $28.3 million expire at various dates from 2026 through 2035. Sections 382 and 383 of the Internal Revenue Code limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

Based on analysis from its inception through December 31, 2017, the Company experienced Section 382 ownership changes in September 2001 and March 2003 and one of its subsidiaries experienced Section 382 ownership changes in January 2006 and January 2011 and the reported deferred tax assets reflect these expected limitations. These ownership changes limited the Company's ability to utilize federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the respective ownership changes of the Company and one of its subsidiaries. Additional ownership changes may occur in the future as a result of events over which the Company will have little or no control, including purchases and sales of the Company's equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of the Company's stock or certain changes in the ownership of any of the Company's 5% stockholders.

A reconciliation of income taxes at the statutory federal income tax rate to net income tax benefit included in the accompanying statements of operations is set forth in the following table:

	Year ended December 31,		
	2018	**2017**	**2016**
U.S. federal income tax benefit at the statutory rate	(21.00)%	(35.00)%	(35.00)%
State income taxes, net of federal taxes	(10.07)	(.03)	.88
Loss in foreign subsidiary	1.20	7.36	15.88
Valuation allowance, including impact of tax reform	18.20	24.10	12.07

Other		
.16		
2.80		
.25		
Total		
(11.51		
)%		
(.77		
)%		
(5.92		
)%		

The loss in foreign subsidiary reconciling item in the above table is the tax effect of intercompany research and development expenses which are not deductible on the Company's consolidated federal income tax return. The state income tax benefit item in the above table is the result of the Company filing amendments in 2018 for certain states for 2014 and 2015 and receiving a refund in 2018.

The Company accounts for the effect of any uncertain tax positions based on a more likely than not threshold to the recognition of the tax positions being sustained based on the technical merits of the position under scrutiny by the applicable taxing authority. If a tax position or positions are deemed to result in uncertainties of those positions, the unrecognized tax position is estimated based on a cumulative probability assessment that aggregates the estimated tax liability for all uncertain tax positions. Interest and penalties assessed, if any, are accrued and recorded in either interest expense or miscellaneous expense, respectively in the consolidated statement of operations. During the year ended December 31, 2018, the Company recorded interest and penalties relating to its uncertain tax position of $82,000 in its consolidated statement of operations in interest expense and other expenses. $335,000 and no interest or penalties were recorded for the years ended December 31, 2017 and 2016, respectively. The liability for uncertain tax benefits consists of estimated federal and state income tax liabilities in years for which the statute of limitations is open. Open years range from 2014 through 2017.

The changes in the Company's uncertain income tax positions for the year ended December 31, 2018 consisted of the following (in thousands):

	December 31, 2018
Beginning Balance - uncertain tax positions	$ 653
Increases for tax positions related to current year	—
Decreases due to settlements with taxing authorities	—
Reductions due to lapsed statute of limitations	—
Ending Balance - uncertain tax positions	$ 653

The Company does not anticipate the liability for uncertain tax positions as of December 31, 2018 to significantly change in the next 12 months.

11. Loss Per Share

The following table presents the calculations of loss per share:

	Years Ended December 31,		
Historical net loss per share	**2018**	**2017**	**2016**
Numerator			
Net loss attributable to common stockholders	$ (53,595)	$ (71,951)	$ (85,155)
Denominator			
Basic and diluted weighted-average shares outstanding	37,191,262	31,304,309	28,979,327
Basic and diluted loss per share	$ (1.44)	$ (2.30)	$ (2.94)

All common stock equivalents are excluded from the computation of diluted loss per share during periods in which losses are reported since the result would be anti-dilutive. For December 31, 2018, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 7,979,644 and 68,585, respectively. For December 31, 2017, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 7,206,884 and 168,221.

12. Licensing Agreements

The Company is a party to a number of licensing agreements with respect to certain of the technologies that underlie its intellectual property. These agreements typically provide that the Company has exclusive rights to the use and sublicensing of the technologies in question for the duration of the intellectual property patent protection in question, subject to the Company meeting its financial and other contractual obligations under the agreements. The Company recognizes expense under its licensing agreements in the period the obligation is incurred. These agreements typically provide for a license fee based on a percent of sales and annual minimum royalties. For additional information regarding how the Company records payments under these agreements, see Note 2 above. The Company has incurred expense of approximately $32,000, $1.4 million, and $2.0 million, under all of the in-licensing agreements for the years ended December 31, 2018, 2017, and 2016, respectively, which is recorded as a component of general and administrative expenses.

Under certain license agreements the Company is obligated to make potential milestone payments as listed in the following table. In addition to the milestone payments, each license is paid as a low single-digit percentage of net sales of the licensed product, subject to annual minimum royalties. These obligations are contingent upon achieving the applicable milestone event, the timing of which cannot presently be determined. The milestone payments and royalty payments are in place through at least the expiration of certain of the Company's patents, which is currently 2029 and beyond.

Licensor	Aggregate potential milestone payments
Augusta University Research Institute under AURI IDO	$2.8 million per licensed product
Public Health Agency of Canada	$250,000

NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

13. Employee Benefit Plans

The Company sponsors a 401(k) plan, which includes a defined contribution feature. The Company's defined contribution was $261,000, $361,000, $482,000 for the years ended December 31, 2018, 2017 and 2016, respectively. The Company made discretionary contributions to the plan of $303,000, $401,000, and $446,000 for the years ended December 31, 2018, 2017 and 2016, respectively.

The Company has approved employment agreements for certain executives, dated October 29, 2010, as amended January 4, 2016, that provide for the payment of 6 to 24 months of base salary, bonus, and group health insurance premiums plus accrued obligations upon termination of the executive in certain circumstances. The agreements include provisions to accelerate the vesting of stock options subject to certain events including those related to a change in control. The Company entered into the January 2016 amendments to the foregoing agreements, upon recommendation by the Compensation Committee of the Board of Directors, to align the terms of certain termination benefits with termination terms for executive officers at similarly situated companies to the Company.

14. Restructuring Charges

The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. Employee severance costs are accrued when the restructuring actions are probable and estimable. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period. The Company also records costs incurred with contract terminations associated with restructuring activities.

In July 2018, the Company completed an organizational review of its clinical programs and reduce its headcount by approximately 30% as compared to June 30, 2018 and made several changes to senior leadership effective July 26, 2018 in order to conserve resources to further advance its clinical development programs. Restructuring expenses of $1.3 million were recorded during 2018, of which $800,000 is included within general and administrative expenses and $500,000 is included within the research and development expenses in the condensed consolidated statement of operations.

In July 2017, the Company undertook an organizational realignment to refocus its clinical development efforts and align the Company's resources to focus on the Company's highest value opportunities. The Company's restructuring activities included a reduction of its workforce by approximately 50%, which consisted primarily of clinical and research and development staff, as well as stopping additional research on the Zika virus. Restructuring charges recorded during 2017 included $1.7 million, of which $1.1 million is included within general and administrative expenses and $600,000 is included within research and development expenses in the consolidated statement of operations. The charges include employee severance costs of one-time employee termination benefits and certain expenses related to contractual termination benefits for employees with pre-existing severance arrangements.

The following table shows the amount accrued for restructuring activities which is recorded within Accrued Expenses in the consolidated balance sheet (in thousands):

	Employee Severance Cost	Total
Balance as of December 31, 2017	$ 207	$ 207
Expensed	1,323	1,323
Cash Payments	881	881
Adjustments	—	—

Balance as of December 31, 2018
$
649

$
649

15. Commitments and Contingencies

From time to time, claims are asserted against the Company arising in the ordinary course of business. In the opinion of management, liabilities, if any, arising from existing claims are not expected to have a material effect on the Company's earnings, financial position, or liquidity.

NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York, or the Court, captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545, or the Securities Action. Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint asserting claims under the federal securities laws against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian, or collectively, the Defendants. The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. In particular, the lead plaintiffs allege that the Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L. The lead plaintiffs do not quantify any alleged damages in the amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. The lead plaintiffs filed an opposition to the motion to dismiss on September 12, 2017. The Defendants filed a reply in support of the motion to dismiss on September 26, 2017. Oral argument was held on October 19, 2017, after which the Court reserved decision.On March 29, 2018, the Court dismissed the amended complaint for failure to state a claim, without prejudice, and gave the lead plaintiffs until May 4, 2018 to file any amended complaint attempting to remedy the defects in their claims. On May 4, 2018, the lead plaintiffs filed a second amended complaint asserting claims under the federal securities laws against the Defendants. Like the first amended complaint, the second amended complaint alleges that the Defendants made material false and/or misleading statements or omissions relating to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L that caused losses to the Company's investors. The lead plaintiffs do not quantify any alleged damages in the second amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the second amended complaint on July 31, 2018. The lead plaintiffs filed an opposition to the motion to dismiss the second amended complaint on September 14, 2018. The Defendants filed a reply in support of the motion to dismiss the second amended complaint on October 9, 2018. Oral argument was held on October 19, 2018, after which the Court reserved decision. On February 13, 2019, the Court dismissed the second amended complaint for failure to state a claim, with prejudice, and closed the case, In the event that the plaintiffs in the Securities Action attempt to continue to pursue their claims, the Company intends to continue defending the Securities Action vigorously.

On or about April 26, 2017, Ronald Morrow filed a shareholder derivative lawsuit on behalf of the Company in the United States District Court for the Southern District of New York, or the Court, against the Company's Chief Executive Officer Charles J. Link, Jr., the Company's Chief Medical Officer and President Nicholas Vahanian, and Company directors Thomas A. Raffin, Joseph Saluri, Ernest J. Talarico, III, Paul R. Edick, Paolo Pucci, and Lota S. Zoth, or collectively, the Morrow Defendants, captioned Morrow v. Link., et al., Case 1:17-cv-03039, or the Morrow Action. The complaint alleges that the Morrow Defendants caused the Company to issue false statements in its 2016 proxy statement regarding risk management and compensation matters in violation of federal securities law. The complaint also asserts state law claims against the Morrow Defendants for breaches of fiduciary duties, unjust enrichment, abuse of control, insider trading, gross mismanagement, and corporate waste, alleging that the Morrow Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L, awarded themselves excessive compensation, engaged in illegal insider trading, and grossly mismanaged the Company. The plaintiff does not quantify any alleged damages in the complaint but seeks restitution for damages to the Company, attorneys' fees, costs, and expenses, as well as an order directing that proposals for strengthening board oversight be put to a vote of the Company's shareholders. The language for such proposals is not specified in the complaint. The plaintiff also contemporaneously filed a statement of relatedness, informing the Court that the Morrow Action is related to Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545. On May 19, 2017, the plaintiff dismissed the Morrow Action without prejudice. Also on May 19, 2017, plaintiffs' counsel in the Morrow Action filed a new shareholder derivative complaint that is substantively identical to the Morrow Action, except that the plaintiff is Rickey Ely. The latter action is captioned Ely v. Link, et

al., Case 17-cv-3799, or the Ely Action. By agreement of the parties and order dated June 26, 2017, the Court temporarily stayed the Ely Action until the Securities Action is dismissed or otherwise finally resolved. Under the terms of the stay, the plaintiff in the Ely Action has until March 15, 2019 (30 days after dismissal of the Securities Action to file an amended derivative complaint or rest upon the current derivative complaint. The Company disputes the claims in the Ely Action and intends to defend against them vigorously.

16. Quarterly Financial Information (Unaudited)

(In thousands, except per share data) Year Ended December 31, 2018	First	Second	Third	Fourth
Grant and licensing revenue	$ 9,900	$ 2,252	$ 120	$ 202
Loss from operations	(18,706)	(17,748)	(15,038)	(10,946)
Net loss	(18,310)	(17,313)	(7,403)	

(10,569
)
Basic and diluted loss per share
$
(.49
)
$
(.47
)
$
(.20
)
$
(.28
)

Year Ended December 31, 2017

Grant and licensing revenue
$
2,761

$
10,370

$
5,482

$
10,098

Loss from operations

(21,198
)

(16,727
)

(20,905
)

(14,051
)

Net loss	(20,913)	(16,726)	(20,626)	(13,686)
Basic and diluted loss per share	$ (.72)	$ (.57)	$ (.69)	$ (.37)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the quarterly period ended March 31, 2019.

o **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the transition period from to .
Commission File Number
001-35342

NEWLINK GENETICS CORPORATION
(Exact name of Registrant as specified in Its Charter)

Delaware	**42-1491350**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2503 South Loop Drive
Ames, Iowa 50010
(515) 296-5555
(Address, including zip code, and telephone number, including area code, of principal executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer ☒
Non-accelerated filer o	Smaller reporting company ☒
Emerging growth company o	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	NLNK	The Nasdaq Stock Market

As of May 6, 2019, there were 37,276,102 shares of the registrant’s Common Stock, par value $0.01 per share, outstanding.

NewLink Genetics Corporation

FORM 10-Q

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PART I – FINANCIAL INFORMATION

PART II – OTHER INFORMATION

PART I

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share data)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 113,184	$ 120,738
Prepaid expenses and other current assets	4,447	5,536
Income tax receivable	341	339
Other receivables	305	459
Total current assets	118,277	127,072
Property and equipment, net	3,520	

3,727

Right-of-use asset

7,334

—

Income tax receivable

140

140

Total non-current assets

10,994

3,867

Total assets
$
129,271

$
130,939

Liabilities and Stockholders’ Equity

Current liabilities:

Accounts payable
$
896

$
555

Accrued expenses

6,950

8,139

Current portion of deferred rent

—

92

Current portion of lease liability

963

—

Current portion of notes payable

63

61

Total current liabilities

8,872

8,847

Long-term liabilities:

Royalty obligation payable to Iowa Economic Development Authority

6,000

6,000

Notes payable

27

43

Lease liability

7,353

—

Deferred rent

—

906

Total long-term liabilities

13,380

6,949

Total liabilities

$

22,252

$	
15,796	

Stockholders’ equity:

Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at March 31, 2019 and December 31, 2018; issued and outstanding shares — 0 at March 31, 2019 and December 31, 2018	
—	
—	
Common stock, $0.01 par value: Authorized shares — 75,000,000 at March 31, 2019 and December 31, 2018; issued 37,387,876 and 37,343,547 at March 31, 2019 and December 31, 2018, respectively, and outstanding 37,276,102 and 37,251,220 at March 31, 2019 and December 31, 2018, respectively	
373	
373	
Additional paid-in capital	
409,143	
407,199	
Treasury stock, at cost: 111,774 and 92,327 shares at March 31, 2019 and December 31, 2018, respectively	
(1,449)	
(1,417)	
Accumulated deficit	
(301,048)	
(291,012)	
Total stockholders’ equity	
$ 107,019	
$ 115,143	
Total liabilities and stockholders’ equity	
$ 129,271	
$ 130,939	

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
Condensed Consolidated Statements
of Operations
(unaudited)
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2019	**2018**
Operating revenues:		
Grant revenue	$ —	$ 9,384
Licensing and collaboration revenue	106	516
Total operating revenues	106	9,900
Operating expenses:		
Research and development	5,203	20,314
General and administrative	5,567	8,292
Total operating expenses	10,770	28,606

Loss from operations	(10,664)	(18,706)	
Other income and expense:			
Miscellaneous income	5	24	
Interest income	624	385	
Interest expense	(1)	(13)	
Other income, net	628	396	
Net loss before taxes	(10,036)	(18,310)	
Income tax benefit	—	—	
Net loss	$ (10,036)	$ (18,310)	
Basic and diluted loss per share			

$	
(0.27	
)	
$	
(0.49	
)	
Basic and diluted average shares outstanding	
37,275,459	
37,155,082	

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
Condensed Consolidated Statement of Stockholders' Equity
(unaudited)
(In thousands, except share data)

Three Month Period ended March 31, 2019

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2018	37,251,220	$ 373	$ 407,199	$ (1,417)	$ (291,012)	$ 115,143
Share-based compensation	—	—	1,944	—	—	1,944
Restricted stock vested	44,329					

—									
—									
—									
—									
—									
Repurchase of common stock									
(19,447)									
—									
—									
(32)									
—									
(32)									
Net loss									
—									
—									
—									
—									
(10,036)									
(10,036)									
Balance at March 31, 2019									
37,276,102									
$ 373									
$ 409,143									
$ (1,449									

)
$
(301,048
)
$
107,019

	Three Month Period ended March 31, 2018					
	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2017	37,109,556	$ 372	$ 389,786	$ (1,142)	$ (237,459)	$ 151,557
Share-based compensation	—	—	4,820	—	—	4,820
Restricted stock vested	84,262	1	105	—	—	106
Repurchase of common stock	(28,720)	—	—	(261)	—	(261)
Cumulative effect of accounting change	—	—	—	—	42	42
Net loss	—	—	—	—	(18,310)	(18,310)
Balance at March 31, 2018	37,165,098	$ 373	$ 394,711	$ (1,403)	$ (255,727)	$ 137,954

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Three Months Ended March 31,	
	2019	**2018**
Cash Flows From Operating Activities		
Net loss	$ (10,036)	$ (18,310)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,944	4,820
Depreciation and amortization	208	334
Gain on sale of fixed assets	(5)	(25)
Amortization of right-of-use assets	(16)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets		

1,088

146

Other receivables

154

330

Accounts payable and accrued expenses

(848
)

(1,907
)
Income taxes receivable

(2
)

17

Unearned revenue

—

(56
)
Deferred rent

—

(25
)
Net cash used in operating activities

(7,513
)

(14,676
)
Cash Flows From Investing Activities

Proceeds on sale of equipment

5

83

Net cash provided by investing activities

5

83	

Cash Flows From Financing Activities

Issuance of common stock, net of offering costs	—
	106
Repurchase of common stock	(32)
	(261)
Principal payments on notes payable	(14)
	(69)
Net cash used in financing activities	(46)
	(224)
Net decrease in cash and cash equivalents	(7,554)
	(14,817)
Cash and cash equivalents at beginning of period	120,738
	158,708
Cash and cash equivalents at end of period	$ 113,184
	$ 143,891

Supplemental disclosure of cash flows information:

Cash paid for interest	$ 1	$ 3
Cash paid (refunds received) for taxes, net	$ 2	$ (17)

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Description of Business

On June 4, 1999, NewLink Genetics Corporation (NewLink) was incorporated as a Delaware corporation. NewLink was formed to develop treatments for patients with cancer and other diseases. NewLink initiated operations in April 2000.

NewLink and its subsidiaries (the Company) are devoting substantially all of their efforts toward research and development. The Company has never earned revenue from commercial sales of its drugs.

The accompanying condensed consolidated financial statements as of March 31, 2019 and for the three months ended March 31, 2019 have been prepared assuming the Company will continue as a going concern. The Company raised net proceeds of $37.6 million from its initial public offering in 2011, completed a follow-on offering of its common stock raising net proceeds of $49.0 million in 2013, and raised an additional $58.7 million in net proceeds from an at the market (ATM) offering completed in 2015.

During 2017, the Company sold 1,940,656 shares of its common stock under an ATM offering, with aggregate net proceeds of $19.3 million after commissions of $398,000 paid to Cantor Fitzgerald & Co. (Cantor) as the placement agent, and other costs of $163,000. In October 2017, the Company sold 5,750,000 of its shares of common stock in a public offering for aggregate net proceeds of $55.2 million after underwriters' discounts, commissions and other expenses of $3.7 million.

The Company's cash and cash equivalents as of March 31, 2019 are expected to be adequate to satisfy the Company's liquidity requirements through 2021. If available liquidity becomes insufficient to meet the Company's operating obligations as they come due, the Company's plans include selling additional shares of common stock, alternative funding arrangements and/or reducing expenditures as necessary to meet the Company's cash requirements. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity. Failure by the Company to successfully execute its plans or otherwise address its liquidity needs may have a material adverse effect on its business and financial position, and may materially affect the Company's ability to continue as a going concern.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared and presented by the Company in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and the rules and regulations of the U.S. Securities and Exchange Commission (the SEC), and, in management's opinion, reflect all adjustments necessary to present fairly the Company's interim condensed financial information.

Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2018, included in the Company's Annual Report on Form 10-K. The financial results for any interim period are not necessarily indicative of financial results for the full year.

3. Significant Accounting Policies

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The condensed consolidated financial statements include the financial statements of NewLink and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

NewLink Genetics Corporation
Notes to Condensed Consolidated Financial Statements
(unaudited)

Financial Instruments and Concentrations of Credit Risk

Cash and cash equivalents, receivables, and accounts payable are recorded at cost, which approximates fair value based on the short-term nature of these financial instruments. The carrying value of notes payable was $90,000 and $104,000 as of March 31, 2019 and December 31, 2018, respectively, which approximate fair value using Level 2 inputs (computed in accordance with ASC 820). The Company is unable to estimate the fair value of the royalty obligation based on future product sales, as the timing of payments, if any, is uncertain.

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, the Company's cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, the Company invests its excess cash primarily in high-quality securities such as certificates of deposit and money market funds.

Property and Equipment

Property and equipment are capitalized as the Company believes they have alternative future uses and are stated at cost, less accumulated depreciation of $7.2 million and $7.0 million as of March 31, 2019 and December 31, 2018, respectively. Depreciation on all property and equipment is calculated on the straight-line method over the shorter of the lease term or estimated useful life of the asset. Computer equipment has useful lives of three to five years, lab equipment has a useful life of five years, and contract manufacturing organization equipment has a useful life of five years.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02 (Topic 842), Leases, to improve financial reporting for leasing transactions. The Company adopted the standard on January 1, 2019 using the modified retrospective method, as required, applying the new standard to all leases existing as of the date of initial application. The Company has elected that the date of the initial application will be the effective date, or January 1, 2019. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. The Company elected the 'package of practical expedients', which permits the Company not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect to apply the use-of-hindsight or the practical expedient pertaining to land easements; as the latter is not applicable to the Company.

Upon adoption of the standard, the Company recorded a lease liability of $8.5 million and a right of use asset of $7.5 million associated with these leases. Included in the right-of-use asset are lease incentives that were previously recorded as deferred rent liability of $1.0 million as of December 31, 2018 on the consolidated balance sheet. There was no material impact to the consolidated statement of operations.

4. Revenues

Revenue Recognition

Revenues are recognized under Topic 606 when control of the promised goods or services is transferred to the Company's customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Prior to transferring the government contracts over to Merck Sharp & Dohme Corp. (Merck) in June 2018, the Company received payments from government entities under its grants and contracts with the Department of Defense and the United States Department of Health and Human Services (HHS). These agreements provided the Company cost reimbursement plus a percentage for certain types of expenditures in return for research and development activities over a contractually defined period. Grant revenues were recognized over time and measured using the input method. The Company used labor costs and subcontractor fees as inputs to measure progress towards satisfying its performance obligations under these agreements. Under this method, the Company recognized revenue generally in the period during which the related costs were incurred, in an amount that reflected the consideration the Company expected to be entitled to in exchange for those goods or services transferred to the government entities due to the government entities' control over the research and development activities.

The grants and contracts with government entities were fully transferred to Merck as of June 2018. Accordingly, during the first quarter of 2019, the Company recognized no grant revenue. The Company had $32,000 and $309,000 of receivables relating to the government contracts on the balance sheet as of March 31, 2019 and December 31, 2018. The Company had $38,000 and $54,000 of accrued expenses for subcontractor fees incurred under the government contracts as of March 31, 2019 and December 31, 2018, respectively.

5. License and Research Collaboration Agreement

Merck Sharp & Dohme Corp.

In November 2014, the Company entered into a licensing and collaboration agreement (the Merck Agreement) with Merck, to develop, manufacture and commercialize rVSV-ZEBOV-GP, an Ebola vaccine the Company licensed from the Public Health Agency of Canada (PHAC). Under the terms of the Merck Agreement, the Company granted Merck an exclusive, royalty bearing license to rVSV-ZEBOV-GP and related technology. Under the Merck Agreement, the Company received a $30.0 million non-refundable, upfront payment in December 2014, and a one-time $20.0 million non-refundable milestone payment in February 2015 upon the initiation of the pivotal clinical trial using the current rVSV-ZEBOV-GP vaccine product as one arm of the trial. In addition, the Company can receive escalating royalties on potential commercial sales by Merck of the current product candidate ranging from single digit to double digits on the rVSV-ZEBOV-GP license agreement product sales and escalating royalties on potential commercial sales by Merck of products other than current products within the Company's patent rights ranging from low to high single digit, on increasing levels of annual net sales worldwide. Merck is expected to lead the development of rVSV-ZEBOV-GP and any other rVSV-based viral hemorrhagic fever vaccine product candidates in order to create a marketable product safe for human use.

The Merck Agreement was amended on December 5, 2017 in connection with our entry into an amended and restated PHAC license on December 5, 2017. The amended Merck Agreement absolves our subsidiary, BioProtection Systems Corporation (BPS), from any future obligation to negotiate or amend the terms of the PHAC license, converts the scope of Merck's sublicense under PHAC's intellectual property rights to be non-exclusive in the Ebola Sudan field of use, and requires Merck to reimburse us in certain circumstances where we may be obligated to pay royalties to PHAC as a result of Merck's product sales but Merck would not otherwise be obligated to pay a royalty to us. On April 26, 2018, the Company entered into an agreement with Merck, the U.S. BioMedical Advanced Research and Development Authority (BARDA), and the Defense Threat Reduction Agency (DTRA) to transfer the government grants from BARDA and DTRA to Merck. The transfer was completed in June 2018 and Merck has replaced the Company as the prime contractor on all such grants.

The Company completed all deliverables under the Merck Agreement in their entirety during the year ended December 31, 2016. For the three months ended March 31, 2019, the Company recognized revenues under the Merck Agreement of $106,000 for work the Company is performing as a subcontractor of Merck under the government contracts that were transferred to Merck. For the three months ended March 31, 2018, the Company recognized license and collaboration revenue under the Merck Agreement of $460,000 for the reimbursement of costs not covered under government contracts.

6. Common Stock Equity Incentive Plan

2009 Equity Incentive Plan

In April 2000, the stockholders approved the Company's 2000 Equity Incentive Plan (the 2000 Plan), and in July 2009, the stockholders approved the Company's 2009 Equity Incentive Plan (the 2009 Plan). Following the approval of the 2009 Plan, no additional stock awards were granted under the 2000 Plan. Shares that remained available for issuance pursuant to the exercise of options or issuance or settlement of stock awards under the 2000 Plan became available for issuance pursuant to the 2009 Plan and all shares that would have otherwise returned to the 2000 Plan became available for issuance pursuant to the 2009 Plan. Under the provisions of the 2009 Plan, the Company may grant the following types of common stock awards:

- Incentive Stock Options
- Nonstatutory Stock Options

- Restricted Stock Awards
- Stock Appreciation Rights

Awards under the 2009 Plan, as amended, may be made to officers, employees, members of the Board of Directors, advisors, and consultants to the Company. As of March 31, 2019, there were 12,400,653 shares of common stock authorized for the 2009 Plan and 1,926,633 shares remained available for issuance.

The following table summarizes the authorized increases of common stock under the 2009 Plan:

Date Authorized	Authorized Shares Added
May 15, 2010	1,238,095
January 7, 2011	714,285
January 1, 2012	823,649
January 1, 2013	839,407
January 1, 2014	1,062,920
January 1, 2015	1,119,233
January 1, 2016	1,152,565
January 1, 2017	1,166,546
January 1, 2018	1,484,382
January 1, 2019	1,490,048

The increases in the authorized shares of common stock under the 2009 Plan in 2010 and 2011 were approved by the Company's stockholders. The increases in the authorized shares of common stock under the 2009 Plan in 2012 through 2019 were made pursuant to an "evergreen provision," in accordance with which, on January 1 of each year, from 2013 to (and including) 2019, a number of shares of common stock in an amount equal to 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or such lesser amount of shares (or no shares) approved by the Company's Board of Directors, was added or will be added to the shares reserved under the 2009 Plan.

2010 Non-Employee Directors' Stock Award Plan

Under the terms of the Company's 2010 Non-Employee Directors' Stock Award Plan (the Directors' Plan) which became effective on November 10, 2011, 238,095 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 161,905 shares of common stock were added to the shares reserved for future issuance under the Directors' Plan. As of March 31, 2019, no shares remain available for issuance under the Directors' Plan.

2010 Employee Stock Purchase Plan

Under the terms of the Company's 2010 Employee Stock Purchase Plan (the 2010 Purchase Plan), which became effective on November 10, 2011, 214,285 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 185,715 shares of common stock were added to the shares

reserved for future issuance under the 2010 Purchase Plan. As of March 31, 2019, 53,509 shares remained available for issuance under the 2010 Purchase Plan.

Share-based Compensation

Share-based compensation expense for the three months ended March 31, 2019 and 2018 was $1.9 million and $4.8 million, respectively. Share-based compensation expense is allocated between research and development and general and administrative expenses within the condensed consolidated statements of operations.

As of March 31, 2019, the total compensation cost related to nonvested option awards not yet recognized was $8.4 million and the weighted-average period over which it is expected to be recognized is 2.6 years.

NewLink Genetics Corporation
Notes to Condensed Consolidated Financial Statements
(unaudited)

Stock Options and Performance Stock Options

The following table summarizes the stock option activity, including options with market and performance conditions, for the three months ended March 31, 2019:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	7,979,644	$ 11.86	4.5
Options granted	1,436,675	1.80	
Options exercised	—	—	
Options forfeited	(25,000)	8.56	
Options expired	(61,060)	21.30	

Outstanding at end of period		
9,330,259	$ 10.26	5.2
Options exercisable at end of period		
6,451,246	$ 12.48	3.3

The Company estimates the fair value of each stock option grant on the date of grant using a Black-Scholes option pricing model. For stock option grants issued with a market condition, the Company used a Monte Carlo simulation valuation model to determine the grant date fair value.

The following table summarizes the range of assumptions used to estimate the fair value of stock options granted, including those options granted with a market condition, during the three months ended March 31, 2019:

Risk-free interest rate	2.6% to 2.7%
Expected dividend yield	—%
Expected volatility	77.6% to 79.5%
Expected term (in years)	4.0 to 7.7
Weighted-average grant-date fair value per share	$1.28

No options were exercised during the three months ended March 31, 2019. The fair value of awards vested during the three months ended March 31, 2019 was $2.1 million.

During the three months ended March 31, 2019, the Company's Board of Directors approved and granted 650,000 shares of equity awards to certain executives with either market or performance conditions. The equity awards had a weighted-average grant date fair value per share of $1.24. The equity awards vest upon the achievement of certain performance conditions. Certain performance conditions relating to the equity awards granted in 2017 were met during the three months ended March 31, 2019 and 79,849 shares vested.

Restricted Stock and Performance Restricted Stock

Restricted stock is common stock that is subject to restrictions, including risks of forfeiture, determined by the planning committee of the Board of Directors in its sole discretion, for as long as such common stock remains subject to any such restrictions. A holder of restricted stock has all rights of a stockholder with respect to such stock, including the right to vote and to receive dividends thereon, except as otherwise provided in the award agreement relating to such award. Restricted stock awards are classified as equity within the consolidated balance sheets. The fair value of each restricted stock grant is estimated on the date of grant using the closing price of the Company's common stock on The Nasdaq Stock Market on the date of grant.

NewLink Genetics Corporation
Notes to Condensed Consolidated Financial Statements
(unaudited)

A summary of the Company's unvested restricted stock, including restricted stock with performance conditions, at March 31, 2019 and changes during the three months ended March 31, 2019 are as follows:

	Number of restricted stock shares	Weighted average grant date fair value
Unvested at beginning of period	68,585	$ 37.75
Granted	—	—
Vested	(44,329)	39.02
Forfeited/cancelled	—	—
Unvested at end of period	24,256	$ 35.43

As of March 31, 2019, the total remaining unrecognized compensation cost related to restricted stock was approximately $673,000 and is expected to be recognized over a weighted-average period of 0.7 years.

The Company does not have a formal policy regarding the source of shares issued upon exercise of stock options or issuance of restricted stock. The Company expects shares issued to be issued from treasury shares or new shares.

7. Leases

The Company has certain facility leases with non-cancellable terms ranging between one and three years, with certain renewal options.

The Company records lease liabilities based on the present value of lease payments over the lease term using an incremental borrowing rate to discount its lease liabilities, as the rate implicit in the lease is typically not readily determinable. To compute the present value of the lease liability, the Company used a weighted-average discount rate of 5%. Certain lease agreements include renewal options that are under the Company's control. The Company includes optional renewal periods in the lease term only when it is reasonably certain that the Company will exercise its option. The weighted-average remaining lease term as of March 31, 2019 is 11.7 years.

The Company does not separate lease components from non-lease components. Variable lease payments include payments to lessors for taxes, maintenance, insurance and other operating costs as well as payments that are adjusted based on an index or rate. The Company's lease agreements do not contain any residual value guarantees or restrictive covenants.

Future minimum lease payments under the non-cancellable operating leases (with initial or remaining lease terms in excess of one year) as of March 31, 2019 are as follows (in thousands):

For the Year Ended December 31:

2019	$	823
2020		1,004
2021		923
2022		906
2023		909
Thereafter		6,570
Total future minimum lease payments	$	11,135
Less: imputed interest		(2,819)
Total	$	8,316

NewLink Genetics Corporation
Notes to Condensed Consolidated Financial Statements
(unaudited)

The following table summarizes the aggregate undiscounted non-cancelable future minimum lease payments for operating leases under the prior lease standard as of December 31, 2018 (in thousands):

For the Year Ended December 31:	
2019	$ 1,105
2020	1,004
2021	923
2022	906
2023	909
Thereafter	6,570
Total	$ 11,417

8. Income Taxes

For the three months ended March 31, 2019 and 2018, the Company recorded no income tax benefit. The income tax benefit for the three months ended March 31, 2019 and 2018 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to a full valuation allowance recorded against anticipated net operating loss carryforwards.

The Company has a noncurrent income tax receivable as of March 31, 2019 for $140,000 which was recorded as an income tax benefit in 2017 and is for the receipt of alternative minimum tax (AMT) credit carryovers. The Tax Cuts and Jobs Act of 2017 (the Tax Act), provides that the AMT credit carryovers are partially refundable beginning in 2018 as an offset to a tax liability. The Company expects the amount to be fully refunded by 2021.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of March 31, 2019 and December 31, 2018, respectively, due to the uncertainty of future recoverability.

The Company has a reserve for uncertain tax positions related to state tax matters of $653,000 as of March 31, 2019 recorded within Accrued Expenses in the condensed consolidated balance sheet, which includes the accrual of interest and penalties. The Company does not expect the amount to change significantly within the next 12 months.

9. Net Loss per Common Share

Basic loss per share is based upon the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted loss per share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average potentially dilutive common stock equivalents during the period when the effect is dilutive.

The following table presents the computation of basic and diluted loss per common share (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2019	2018
Loss attributable to common stockholders	$ (10,036)	$ (18,310)
Basic and diluted weighted-average shares outstanding	37,275,459	37,155,082
Basic and diluted loss per share	$ (0.27)	$ (0.49)

All common stock equivalents are excluded from the computation of diluted loss per share during periods in which losses are reported since the result would be anti-dilutive. As of March 31, 2019, anti-dilutive stock options

and restricted stock awards excluded from our calculation totaled 9,330,259 and 24,256, respectively. As of March 31, 2018, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 8,369,519 and 100,719, respectively.

10. Restructuring Charges

The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. Employee severance costs are accrued when the restructuring actions are probable and estimable. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits, is recognized ratably over the future service period. The Company also records costs incurred with contract terminations associated with restructuring activities.

In July 2018, the Company completed an organizational review of its clinical programs and reduced its headcount by approximately 30% as compared to June 30, 2018 and made several changes to senior leadership effective July 26, 2018 in order to conserve resources to advance its clinical development programs. No restructuring charges were recorded during the three months ended March 31, 2019.

The following table shows the amount accrued for restructuring activities which is recorded within Accrued Expenses in the condensed consolidated balance sheet (in thousands):

	Employee Severance Cost	Total
Balance as of December 31, 2018	$ 649	$ 649
Expensed	—	—
Cash Payments	214	214
Balance as of March 31, 2019	$ 435	$ 435

11. Commitments and Contingencies

From time to time, claims are asserted against the Company arising in the ordinary course of business. In the opinion of management, liabilities, if any, arising from existing claims are not expected to have a material effect on the Company's earnings, financial position, or liquidity.

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York (the Court), captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545 (the Securities Action). Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint asserting claims under the federal securities laws against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian, (collectively, the Defendants). The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. On March 29, 2018, the Court dismissed the amended complaint for failure to state a claim, without prejudice, and gave the lead plaintiffs until May 4, 2018 to file any amended complaint attempting to remedy the defects in their claims. On May 4, 2018, the lead plaintiffs filed a second amended complaint asserting claims under the federal securities laws against the Defendants. Like the first amended complaint, the second amended complaint alleges that the Defendants made material false and/or misleading statements or omissions relating to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L that caused losses to the Company's investors. The lead plaintiffs do not quantify

any alleged damages in the second amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the second amended complaint on July 31, 2018. On February 13, 2019, the Court dismissed the second amended complaint for

failure to state a claim, with prejudice, and closed the case. On March 14, 2019, lead plaintiffs filed a notice of appeal. The court set a schedule in which appellants' (plaintiffs) brief is due May 17, 2019, appellees' (defendants) brief is due June 21, 2019, and appellants may file a reply no later than July 8, 2019. The Company intends to continue defending the Securities Action vigorously.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and such statements are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information available to our management as of the date hereof. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: our ongoing and planned preclinical studies and clinical trials; the timing of the release of the results of data from ongoing preclinical studies and clinical trials; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the clinical utility of our product candidates; our plans to leverage our existing technologies to discover and develop additional product candidates; our ability to quickly and efficiently identify and develop product candidates; our intellectual property position; the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; plans to develop, commercialize, market and manufacture our product candidates; and other risks and uncertainties, including those described in Part II, Item 1A, "Risk Factors" of this Quarterly Report and in our other periodic reports filed from time to time with the Securities and Exchange Commission, or SEC, including our Annual Report on Form 10-K for the year ended December 31, 2018. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including those risks. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Overview

NewLink Genetics Corporation (the Company, NewLink, we, our or us) is a clinical-stage immuno-oncology company focused on developing novel immunotherapeutic products for the treatment of patients with cancer. Our leading small-molecule product candidates currently in clinical development target the indoleamine-2, 3-dioxygenase (IDO) pathway, which is one of the key pathways for cancer immune escape. These product candidates, indoximod and NLG802 (a prodrug of indoximod), are IDO pathway inhibitors with mechanisms of action that center around breaking the immune system's tolerance to cancer. We also have an additional small molecule product candidate, NLG207 (formerly CRLX101), which is a nanoparticle-drug conjugate (NDC) consisting of a cyclodextrin-based polymer backbone linked to camptothecin, a topoisomerase 1 inhibitor.

Based on early clinical data from our Phase ½ clinical trials, our clinical program is focused on targeted indications with great unmet need where indoximod, NLG802, and NLG207 have produced encouraging early data. We plan to advance our core clinical programs and expect to present additional data supporting these research efforts in 2019. We anticipate presenting updated Phase 1 data for indoximod in both front-line diffuse intrinsic pontine glioma (DIPG) and our indoximod prodrug, NLG802.

IDO Pathway Inhibitors

In cancer, the IDO pathway regulates immune response by suppressing T-cell activation, which enables cancer to avoid immune response. IDO is overexpressed in many cancers, both within tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor-draining lymph nodes, thereby promoting peripheral tolerance to tumor associated antigens (TAAs). When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system.

The IDO pathway refers to a series of reactions initiated by IDO that result in the reduction of the amino acid tryptophan in the local tumor environment. We believe the local presence of tryptophan in adequate concentrations

promotes antitumor T-cells, and the local reduction of tryptophan combined with the presence of the breakdown product of tryptophan metabolism, kynurenine, is understood to suppress the activation of T-cells. Preclinical and, increasingly, clinical data suggest that IDO pathway inhibitors may also enhance the anti-tumor effects of other immunotherapies, chemotherapies and radiation when used as a combination therapy for patients with cancer.

We have a clinical development program primarily focused on the IDO pathway. Our small-molecule IDO pathway inhibitor product candidates currently in clinical development include indoximod and NLG802. Our product candidates are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. Indoximod acts as a tryptophan mimetic, thereby signaling the activation of antitumor T-cells by the activation of mammalian target of rapamycin (mTOR), acts directly on T-cells, and modulates aryl hydrocarbon receptor (AhR)-mediated effects.

We have observed an encouraging safety profile for our IDO pathway inhibitors. They are also orally bioavailable and we believe they offer the potential to be synergistic with other therapies such as radiation, chemotherapy, vaccination and immunotherapies involving other checkpoint inhibitors such as anti-PD-1, anti-programmed cell death ligand-1 (PD-L1), or anti-cytotoxic T-lymphocyte antigen 4 (CLTA4). Clinical data suggest an increase in clinical activity without adding significant toxicity.

Indoximod

Indoximod, our lead IDO pathway inhibitor, is currently in clinical development in combination with other cancer therapeutics for patients with DIPG, acute myeloid leukemia, and melanoma. We believe there may be additional opportunities to apply indoximod to a broader set of cancer indications. More than 900 patients have been treated with indoximod to date and it has generally been well-tolerated, including in combination with PD-1 checkpoint inhibitors, various chemotherapy agents, radiation, and a cancer vaccine.

A tablet formulation of indoximod hydrochloride has been developed for adult patients and a sprinkle formulation is being developed for pediatric indications. We plan to use our new tablet formulation of indoximod in future clinical trials.

Two U.S. patents covering both the salt and prodrug formulations of indoximod were issued in the U.S. on August 15, 2017 and February 19, 2019 providing exclusivity until at least 2036. We are currently pursuing international patent coverage for these formulations.

NLG802

NLG802 is a prodrug of indoximod. NLG802 is intended to increase bioavailability and exposure to indoximod above levels currently achievable by direct oral administration of indoximod. We filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA), in the first quarter of 2017 and the first patient was dosed with NLG802 in a Phase 1 clinical trial in July 2017. The purpose of this Phase 1 trial is to assess preliminary safety and to determine the recommended dose for subsequent Phase 2 evaluations. NLG802 is a new chemical entity with patent coverage into 2036. We are also pursuing international patent coverage for NLG802.

NLG919

NLG919, a direct enzymatic inhibitor, was previously in clinical development as part of our collaboration with Genentech, Inc. (Genentech). In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech (the Genentech Agreement). The Genentech Agreement provided for the development and commercialization of NLG919. On December 6, 2017, the Genentech Agreement with respect to NLG919 was terminated. As part of the partial termination, worldwide rights to NLG919 reverted to us and Genentech granted us a license under certain of Genentech’s intellectual property to develop and commercialize NLG919. We continue to explore the potential for further development and licensing opportunities but do not have an active program for the drug product candidate as of March 31, 2019.

Under the Genentech Agreement, we conducted a two-year pre-clinical research program with Genentech to discover novel next-generation IDO/tryptophan-2, 3-dioxygenase (TDO) inhibitors. The research program ended in November 2016, and we received notice on May 9, 2018 that Genentech would not continue the collaboration with respect to next generation IDO/TDO inhibitors identified through the research program. The Genentech Agreement was terminated in its entirety on November 6, 2018 and we received control of the intellectual property portfolio related to the newly discovered TDO inhibitors, IDO inhibitors and dual IDO/TDO inhibitors.

Additional Product Candidates

NLG207

NLG207 is a NDC consisting of a cyclodextrin-based polymer backbone linked to camptothecin, a topoisomerase-1, or top-1, inhibitor. Because the vasculature in tumors is more permeable than normal tissue, we believe NDCs have the potential to enhance drug delivery to tumors by enabling gradual payload release inside cancer cells to augment antitumor activity while reducing off-target toxicity. NLG207 has been studied in more than 400 patients as monotherapy or in combination with other anticancer agents for patients with solid tumors.

A Phase 2 trial evaluating NLG207 plus paclitaxel for patients with recurrent ovarian, fallopian tube or primary peritoneal cancer was completed in collaboration with the Gynecological Oncology Group and the results of the trial were presented at the annual meeting for the American Association for Cancer Research on April 2, 2019.

Ebola Vaccine Candidate

In November 2014, we entered into the Merck Agreement to develop and potentially commercialize our rVSVΔG-ZEBOV-GP vaccine product candidate and other aspects of our vaccine technology. The rVSVΔG-ZEBOV-GP vaccine product candidate was originally developed by the Public Health Agency of Canada (PHAC) and is designed to utilize the rVSV vector to induce immunity against Ebola virus when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. Under the Merck Agreement, we received an upfront payment of $30.0 million in October 2014, and in February 2015 we received a milestone payment of $20.0 million. We have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved by the FDA and successfully commercialized by Merck. rVSVΔG-ZEBOV-GP is also eligible to receive a priority review voucher and we are entitled to a portion of the value of the voucher if it is granted. In addition to milestone payments from Merck, we were awarded contracts for development of the rVSVΔG-ZEBOV-GP from the U.S. BioMedical Advanced Research & Development Authority (BARDA), and the Defense Threat Reduction Agency (DTRA), totaling $52.1 million during 2016 and $67.0 million during 2014 and 2015. Funds of $2.1 million were de-obligated from the DTRA grant awards in 2017. We have received total awards of $118.8 million.

On April 26, 2018 we entered into an agreement with Merck, DTRA and BARDA to transfer the government grants from BARDA and DTRA to Merck. The transfer was completed in June 2018 and Merck has replaced us as the prime contractor on all such grants.

Restructuring Charges

In July 2018, the Company completed an organizational review of its clinical programs and reduced its headcount by approximately 30% as compared to June 30, 2018 and made several changes to senior leadership effective July 26, 2018 in order to conserve its resources. No restructuring charges were recorded during the three months ended March 31, 2019 relating to this reorganization.

Corporate Information

Founded in 1999, our executive offices and manufacturing facilities are located in the Iowa State University Research Park in Ames, Iowa. We have approximately 26,616 square feet, comprising executive office space and space dedicated to manufacturing, testing and product storage, leased with the Iowa State University Research Park Corporation. We have additional executive and administrative space in Austin, Texas and clinical, regulatory and executive offices in Wayne, Pennsylvania.

We incurred a net loss of $10.0 million for the three months ended March 31, 2019. We expect to continue to incur losses over the next several years as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

Critical Accounting Policies and Significant Judgments and Estimates

We have prepared our financial statements in accordance with U.S. GAAP which requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, expenses and related disclosures at the date of the financial statements, as well as revenues and expenses during the reporting periods. As such, to understand our financial statements, it is important to understand our critical accounting policies. A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and

requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Actual results could, therefore, differ materially from these estimates under different assumptions or conditions.

Our Annual Report on Form 10-K for the year ended December 31, 2018 discusses our most critical accounting policies. Since December 31, 2018, there have been no material changes in the critical accounting policies discussed in our 2018 Annual Report.

Recent Accounting Pronouncements

We adopted ASC Topic 842 on January 1, 2019 and have disclosed the impact adoption had on our condensed consolidated financial statements within Note 3 of the "Notes to Condensed Consolidated Financial Statements" of this Form 10-Q. We do not believe that any other recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

Results of Operations

Comparison of the Three Months Ended March 31, 2019 and 2018

Revenues. Revenues for the three months ended March 31, 2019 were $106,000, a decrease of $9.8 million from $9.9 million for the same period in 2018. The decrease in revenue was due to a decrease in grant revenue of $9.4 million, primarily attributable to a decrease in billings under the government grant contracts which were fully transferred to Merck in June 2018, and a decrease of $410,000 in licensing revenue, attributable to lower billings to Merck. We recognized licensing revenue during the three months ended March 31, 2019 for work we performed as a subcontractor of Merck.

Research and Development Expenses. Research and development expenses for the three months ended March 31, 2019 were $5.2 million, a decrease of $15.1 million from $20.3 million for the same period in 2018. The decrease was primarily due to reductions of $9.9 million in contract research and manufacturing spend, $2.2 million in personnel-related and stock compensation expense, $2.1 million in clinical trial expense, $500,000 in supplies and licensing, and $400,000 in legal and consulting expense.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2019 were $5.6 million, a decrease of $2.7 million from $8.3 million for the same period in 2018. The decrease was due primarily to reductions of $2.1 million in personnel-related and stock compensation expense, $605,000 in legal and consulting expense, offset by an increase of $72,000 in supplies and travel expense.

Income Tax Benefit. We did not record any income tax benefit for the three months ended March 31, 2019 and 2018, respectively.

Net Loss. The net loss for the three months ended March 31, 2019 was $10.0 million compared to a net loss of $18.3 million for the same period in 2018. The basic and diluted weighted-average common shares outstanding for the three months ended March 31, 2019 were 37,275,459, resulting in a basic and diluted loss per share of $0.27. For the three months ended March 31, 2018, the basic and diluted weighted-average common shares outstanding were 37,155,082, resulting in basic and diluted loss per share of $0.49.

Liquidity and Capital Resources

As of March 31, 2019, we had cash and cash equivalents of $113.2 million. We have historically funded our operations principally through the private placement of equity securities, public offerings of common stock, and license and milestone payments received under our collaboration agreements. We believe that our cash and cash equivalents on hand will be sufficient to fund our operations through 2021.

With the exception of fiscal year 2014, we have incurred operating losses and an accumulated deficit as a result of ongoing research and development spending since inception. We anticipate that we will continue to generate operating losses as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

We may seek to sell additional equity or debt securities or obtain a credit facility if our available cash and cash equivalents are insufficient to satisfy our liquidity requirements or if we develop additional opportunities to do so. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise

additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research and development activities, which could harm our business.

Because of the numerous risks and uncertainties associated with the research and development of our product candidates, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results, and costs of clinical trials for our product candidates, and discovery and development activities related to new product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales, facilities, and distribution costs;
- the cost of manufacturing our product candidates and any products we commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- whether, and to what extent, we are required to repay our outstanding government provided loans;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

We believe that our cash and cash equivalents on hand will be sufficient to fund our operations through 2021.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Three Months Ended March 31,	
	2019	**2018**
Net cash used in operating activities	$ (7,513)	$ (14,676)
Net cash provided by investing activities	5	83
Net cash used in financing activities	(46)	(224)
Net decrease in cash and equivalents	$ (7,554)	$ (14,817)

For the three months ended March 31, 2019 and 2018, we used cash of $7.5 million and $14.7 million, respectively, for our operating activities. The decrease in cash used in operating activities was primarily due to the decrease in research and development activity and changes in working capital for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018.

For the three months ended March 31, 2019 and 2018, our investing activities provided cash of $5,000 and $83,000, respectively. The cash provided by investing activities during the three months ended March 31, 2019 was due to proceeds received from sales of property and equipment of $5,000. The cash provided by investing activities during the three months ended March 31, 2018 was due to proceeds received from sales of property and equipment of $83,000.

For the three months ended March 31, 2019 and 2018, our financing activities used cash of $46,000 and $224,000, respectively. The cash used in financing activities during the three months ended March 31, 2019 was due to the net payments made on long-term obligations and notes payable of $14,000 and repurchases of common stock of $32,000. The cash provided by financing activities during the three months ended March 31, 2018 was primarily due to the issuance of common stock for net proceeds of $106,000, offset by net payments on long-term obligations and notes payable of $69,000, and repurchase of common stock of $261,000.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of March 31, 2019 and December 31, 2018, we had cash and cash equivalents of $113.2 million and $120.7 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

Our long-term debt bears interest at fixed rates. Any change in interest rates would have an immaterial impact on our financial statements.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company's principal executive officer and principal financial officer have concluded, based on an evaluation of the Company's disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) or 15d-15(e)) as required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15 that, as of March 31, 2019, the Company's disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

In connection with the evaluation of the Company's internal control over financial reporting that occurred during the quarter ended March 31, 2019, which is required under the Securities Exchange Act of 1934 by paragraph (d) of Exchange Rules 13a-15 or 15d-15 (as defined in paragraph (f) of Rule 13a-15), management determined that there was no change that materially affected or is reasonably likely to materially affect internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York (the Court), captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545 (the Securities Action). Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint asserting claims under the federal securities laws against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian (collectively, the Defendants). The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. On March 29, 2018, the Court dismissed the amended complaint for failure to state a claim, without prejudice, and gave the lead plaintiffs until May 4, 2018 to file any amended complaint attempting to remedy the defects in their claims. On May 4, 2018, the lead plaintiffs filed a second amended complaint asserting claims under the federal securities laws against the Defendants. Like the first amended complaint, the second amended complaint alleges that the Defendants made material false and/or misleading statements or omissions relating to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L that caused losses to the Company's investors. The lead plaintiffs do not quantify any alleged damages in the second amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the second amended complaint on July 31, 2018. On February 13, 2019, the Court dismissed the second amended complaint for failure to state a claim, with prejudice, and closed the case. On March 14, 2019, lead plaintiffs filed a notice of appeal. The court set a schedule in which appellants' (plaintiffs) brief is due May 17, 2019, appellees' (defendants) brief is due June 21, 2019, and appellants may file a reply no later than July 8, 2019. The Company intends to continue defending the Securities Action vigorously.

On or about April 26, 2017, Ronald Morrow filed a shareholder derivative lawsuit on behalf of the Company in the Court, against the Company's Chief Executive Officer Charles J. Link, Jr., the Company's Chief Medical Officer and President Nicholas Vahanian, and Company directors Thomas A. Raffin, Joseph Saluri, Ernest J. Talarico, III, Paul R. Edick, Paolo Pucci, and Lota S. Zoth (collectively, the Morrow Defendants), captioned Morrow v. Link., et al., Case 1:17-cv-03039 (the Morrow Action). The complaint alleges that the Morrow Defendants caused the Company to issue false statements in its 2016 proxy statement regarding risk management and compensation matters in violation of federal securities law. The complaint also asserts state law claims against the Morrow Defendants for breaches of fiduciary duties, unjust enrichment, abuse of control, insider trading, gross mismanagement, and corporate waste, alleging that the Morrow Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L, awarded themselves excessive compensation, engaged in illegal insider trading, and grossly mismanaged the Company. The plaintiff does not quantify any alleged damages in the complaint but seeks restitution for damages to the Company, attorneys' fees, costs, and expenses, as well as an order directing that proposals for strengthening board oversight be put to a vote of the Company's shareholders. The language for such proposals is not specified in the complaint. The plaintiff also contemporaneously filed a statement of relatedness, informing the Court that the Morrow Action is related to Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545. On May 19, 2017, the plaintiff dismissed the Morrow Action without prejudice. Also on May 19, 2017, plaintiffs' counsel in the Morrow Action filed a new shareholder derivative complaint that is substantively identical to the Morrow Action, except that the plaintiff is Rickey Ely. The latter action is captioned Ely v. Link, et al., Case 17-cv-3799 (the Ely Action). By agreement of the parties and order dated June 26, 2017, the Court temporarily stayed the Ely Action until the Securities Action is dismissed or otherwise finally resolved. Under the terms of the stay, the plaintiff in the Ely Action has until March 15, 2019 (30 days after dismissal of the Securities Action with prejudice) to file an amended derivative complaint or rest upon the current derivative complaint. By further agreement of the parties, dated March 15, 2019, the Ely Action will continue to be stayed pending the outcome of the appeal in the Securities Action. If the Securities Action continues to be dismissed in its entirety following its appeal plaintiff in the Ely Action has agreed to withdraw or dismiss the action, with prejudice. The Company disputes the claims in the Ely Action and intends to defend against them vigorously.

Item 1A. RISK FACTORS

RISK FACTORS

Investing in our common stock involves significant risks, some of which are described below. In evaluating our business, investors should carefully consider the following risk factors. These risk factors contain, in addition to historical information, forward-looking statements that involve substantial risks and uncertainties. Our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below. The order in which the following risks are presented is not intended to reflect the magnitude of the risks described. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Business Risks

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them. We have not completed testing of any of our product candidates in controlled clinical trials.

The clinical development and regulatory approval process is expensive and time-consuming. The timing of any future product approval cannot be accurately predicted. If we fail to obtain regulatory approval for our current or future product candidates, we will be unable to market and sell them, and therefore we may never be profitable.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required varies depending on the product candidate, the condition being evaluated, the trial results and regulations applicable to any particular product candidate. Any inability to successfully complete preclinical and clinical development could result in additional costs to us.

Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Initial results may not be confirmed upon full analysis of the detailed results of a trial. Product candidates in later-stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

We are heavily dependent on the success of the clinical development of indoximod, and if we fail to complete clinical trials, fail to demonstrate safety and efficacy in those clinical trials, fail to obtain regulatory approval or fail to commercialize indoximod successfully, our business, financial condition and results of operations would be harmed.

The indoximod clinical development program currently encompasses a number of Phase 1 and 2 combination trials across multiple cancer indications. If we fail to complete any of these trials or fail to obtain regulatory approval, our ability to commercialize indoximod will be materially and adversely affected and our business, financial condition and results of operations would be harmed.

If we make changes to any of our product candidates, additional clinical trials may be required resulting in additional costs and delays.

We have an ongoing research program to investigate potential opportunities to improve the potency, efficacy and/or safety profile of some of our product candidates through modifications to their formulations or chemical compositions. These efforts may not be successful. If a new formulation or composition appears promising, we may decide to undertake clinical development of such formulation or composition even if an existing product candidate has shown acceptable safety and efficacy in clinical trials. The nature and extent of additional clinical trials that might be required for a new formulation or composition would depend on many factors. If we were to decide to pursue clinical development of a new formulation or composition, we would incur additional costs and the timeline for

potential commercialization would be delayed. There can be no assurance that any new formulation or composition would prove to be safe or effective or superior to an existing product candidate. Any delay in commercialization of a new formulation or composition may adversely affect our competitive position.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle, including by allowing IND applications to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. Furthermore, our resource allocation decisions and our decisions about whether and how to develop or commercialize any particular product candidate may be based on evaluations of the scientific and commercial potential or target market for the product candidate that later prove to be materially inaccurate. If we enter into collaborations, licensing or other royalty arrangements to develop or commercialize a particular product candidate, we may relinquish valuable rights to that product candidate in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

We may face delays in completing our clinical trials, or we may not be able to complete them at all.

We have not completed all of the clinical trials necessary to support an application with the FDA for approval to market any of our product candidates. Our current and future clinical trials may be delayed or terminated as a result of many factors, including:

- we may experience delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- we may need to reformulate or change the dosing of our product candidates;
- our clinical trials may have slower than expected patient enrollment or lack of a sufficient number of patients that meet their enrollment criteria;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;
- we may experience difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our clinical trial protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials;
- our third-party contractors, including those manufacturing our product candidates or components of ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- we may experience governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines;

- enrollment in and conduct of our clinical trials may be adversely affected by the regulatory approval of competing agents in this class, competition with ongoing clinical trials or scheduling conflicts with participating clinicians; and
- we may experience delays in achieving clinical trial endpoints and completing data analysis for a trial.

In addition, we rely on academic institutions, physician practices and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other aspects of these clinical trials than if we conducted the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol or applicable regulations. We also may rely on clinical research organizations to perform our data management and analysis. They may not provide these services as required or in a timely or compliant manner.

Moreover, our development costs will increase if we are required to complete additional or larger clinical trials for our product candidates prior to FDA approval. If the delays or costs are significant, our financial results and ability to commercialize our product candidates will be adversely affected.

If we encounter difficulties enrolling patients in our clinical trials, our clinical trials could be delayed or otherwise adversely affected.

Clinical trials for our product candidates require us to identify and enroll a large number of patients with the disease under investigation, or healthy volunteers willing to participate in certain trials. We may not be able to enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a clinical trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- changes in the standard of care that make the trial as designed less attractive to clinicians and patients;
- availability of competing therapies and clinical trials, including announced clinical trials evaluating potentially competing IDO pathway inhibitors in clinical settings similar to our clinical trials;
- the results of clinical trials of other IDO pathway inhibitors;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Regulatory authorities may not approve our product candidates even if they meet safety and efficacy endpoints in clinical trials.

We have discussions with and obtain guidance from regulatory authorities regarding certain aspects of our clinical development activities. These discussions are not binding commitments on the part of regulatory authorities. Under certain circumstances, regulatory authorities may revise or retract previous guidance during the course of our clinical activities or after the completion of our clinical trials. A regulatory authority may also disqualify a clinical trial in whole or in part from consideration in support of approval of a potential product for commercial sale or otherwise deny approval of that product. Prior to regulatory approval, a regulatory authority may elect to obtain advice from outside experts regarding scientific issues and/or marketing applications under a regulatory authority review. In the United States, these outside experts are convened through the FDA's Advisory Committee process,

which would report to the FDA and make recommendations that may differ from the views of the FDA. The FDA is not bound by the recommendations of an Advisory Committee, but it typically follows such recommendations. In addition, should an Advisory Committee be convened, it would be expected to lengthen the time for obtaining regulatory approval, if such approval is obtained at all.

The FDA and other foreign regulatory agencies can delay, limit or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- our manufacturing processes or facilities may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional work on our part.

Any delay in, or failure to receive or maintain, approval for any of our product candidates could prevent us from ever generating meaningful revenues or achieving profitability in future years.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may change requirements for approval even after a clinical trial design has been approved. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

Under the Merck Agreement, we have ongoing obligations related to the development of our Ebola vaccine product candidate, which may result in greater costs and a longer timeframe for regulatory approval than we estimate, yet we will receive limited revenues, if any, from any future sales of our Ebola vaccine product candidate.

Under the Merck Agreement, we have ongoing obligations related to the development of our Ebola vaccine product candidate, including obligations related to clinical trials, government contracting and licensing of the vaccine technology, which may cause us to incur costs or losses materially larger than we expect. However, because we have exclusively licensed the right to research, develop, manufacture and distribute our Ebola vaccine product candidate to Merck and we are only entitled to certain royalty and other payments under the Merck Agreement, we will receive limited revenues, if any, even if we or Merck are successful in developing and commercializing our Ebola vaccine product candidate.

The time and cost of product development and the timeframe for regulatory approval of any Ebola vaccine product candidate are uncertain and may be longer and more costly than we estimate. Our Ebola vaccine product candidate is a live virus based on vesicular stomatitis virus (VSV). There are no commercial vaccines based upon this virus, and unforeseen problems related to the use of our live virus vaccine may prevent or materially increase costs and delays of further development or approval of our Ebola vaccine product candidate. There may be unknown safety risks associated with the vaccine, and regulatory agencies such as the FDA may require us to conduct extensive safety testing prior to approval to demonstrate a low-risk of rare and severe adverse events caused by the vaccine.

Public perception of vaccine safety issues, including adoption of novel vaccines based upon VSV, may adversely influence willingness of subjects to participate in clinical trials, or if approved, of physicians to prescribe, and of patients to receive, novel vaccines. For example, our Ebola vaccine product candidate is currently being developed for the prevention of, and may later be developed for the treatment of patients infected with, Ebola, and public aversion to vaccines for Ebola or vaccines in general may adversely influence later-stage clinical trials of this product candidate or, if approved, its commercial success.

Even if approved, a number of factors may adversely affect commercial sales. Lack of familiarity with the viral vaccine and potential adverse events associated with vaccination may adversely affect physician and patient perception and uptake of our potential product. Furthermore, there are no assurances that the vaccine will be approved for inclusion in government stockpile programs, which may be material to the commercial success of the product candidate, either in the United States or abroad. If our Ebola vaccine product candidate eventually is approved and sold commercially, we will receive limited revenues under the Merck Agreement. Finally, in certain cases, our obligations to pay royalties to PHAC may exceed the royalties we receive from Merck.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's Good Clinical Practice (GCP) requirements, or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and Institutional Review Boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under current Good Manufacturing Practice (cGMP) requirements and may require large numbers of test subjects. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- the product candidate may have unforeseen adverse side effects;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- failure to demonstrate a benefit from using a drug;
- the quality or stability of the product candidate may fall below acceptable standards; or
- insufficient quantities of the product candidate to complete the trials.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors indoximod, NLG802, NLG207, NLG919, and other product candidates could take significantly longer to gain regulatory approval than we expect or we may never gain approval for additional indications, which could reduce our revenue by delaying or terminating their commercialization.

Some of our product candidates have been studied, or in the future may be studied, in clinical trials co-sponsored by organizations or agencies other than us, or in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.

We supplied indoximod in support of a Phase 2 investigator-initiated clinical trial, and we provided clinical supply of dorgenmeltucel-L in support of a Phase 2 investigator-initiated clinical trial. Our Ebola vaccine product candidate was studied in clinical trials in West Africa. We may continue to supply and otherwise support similar trials in the future. However, because we are not the sponsors of these trials, we do not control the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment, and, as a result, are subject to risks associated with the way these types of trials are conducted, in particular should any problems arise. These risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data.

If we cannot demonstrate the safety of our product candidates in preclinical and/or other non-clinical studies, we will not be able to initiate or continue clinical trials or obtain approval for our product candidates.

In order to move a product candidate not yet being tested in humans into a clinical trial, we must first demonstrate in preclinical testing that the product candidate is safe. Furthermore, in order to obtain approval, we must also demonstrate safety in various preclinical and non-clinical tests. We may not have conducted or may not conduct in the future the types of preclinical and other non-clinical testing ultimately required by regulatory authorities, or future preclinical tests may indicate that our product candidates are not safe for use in humans. Preclinical testing is expensive, can take many years and can have an uncertain outcome. In addition, success in initial preclinical testing does not ensure that later preclinical testing will be successful. We may experience numerous unforeseen events during, or as a result of, the preclinical testing process, which could delay or prevent our ability to develop or commercialize our product candidates, including:

- our preclinical testing may produce inconclusive or negative safety results, which may require us to conduct additional preclinical testing or to abandon product candidates that we believed to be promising;

- our product candidates may have unfavorable pharmacology, toxicology or carcinogenicity;
- our product candidates may cause undesirable side effects; and
- the FDA or other regulatory authorities may determine that additional safety testing is required.

Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition and results of operations.

Even if ultimately approved, indoximod, NLG802, NLG207, NLG919, our Ebola vaccine product candidate or any other potential product we or our collaborators may commercialize and market may be later withdrawn from the market or subject to promotional limitations.

We or our collaborators may not be able to obtain the labeling claims necessary or desirable for the promotion of any potential future products. We or our collaborators may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory, the FDA or a comparable agency in a foreign country may withdraw marketing authorization or may condition continued marketing on commitments from us or our collaborators that may be expensive and/or time-consuming to fulfill. In addition, if we or others identify adverse side effects after any of our potential products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our potential products, additional clinical trials, changes in labeling of our potential products and/or additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of our potential products.

We will need to develop or acquire additional capabilities in order to commercialize any product candidates that obtain FDA approval, and we may encounter unexpected costs or difficulties in doing so.

We will need to acquire additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. Currently, we have limited experience in preparing applications for marketing approval, commercial-scale manufacturing, managing large-scale information technology systems or managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources.

To do this effectively, we must:

- train, manage and motivate a growing employee base;
- accurately forecast demand for our products; and
- expand existing operational, financial and management information systems.

We will need to increase our manufacturing capacity, which may include negotiating and entering into additional third-party agreements to meet our commercial manufacturing requirements.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate significant product revenue.

We do not have a sales organization and have no experience in the sales and distribution of pharmaceutical products. There are risks involved with establishing our own sales capabilities and increasing our marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us could potentially be lower than if we market and sell these products ourselves.

We entered into the Merck Agreement in November 2014 for the research, development, manufacture and distribution of our Ebola vaccine product candidate. Even if our Ebola vaccine product candidate is approved by regulators for marketing and sale, Merck may be unsuccessful in its efforts to commercialize our Ebola vaccine product candidate, respectively, or may devote fewer resources to such efforts than we would consider optimal.

We may establish our own specialty sales force and/or engage other biopharmaceutical or other healthcare companies with established sales, marketing and distribution capabilities to sell, market and distribute any future

products. We may not be able to establish a specialty sales force or establish sales, marketing or distribution relationships on acceptable terms. Factors that may inhibit our efforts to commercialize any future products without strategic collaborators or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to an adequate number of physicians to educate them about the attributes of any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Because the establishment of sales, marketing and distribution capabilities depends on the progress toward commercialization of our product candidates, and because of the numerous risks and uncertainties involved with establishing those capabilities, we are unable to predict when, if ever, we will establish our own sales, marketing and distribution capabilities. If we are not able to collaborate with third parties and are unsuccessful in recruiting sales, marketing and distribution personnel or in building the necessary infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

Failure to attract and retain key personnel could impede our ability to develop our products and to obtain new collaborations or other sources of funding.

Because of the specialized scientific nature of our business, our success is highly dependent upon our ability to attract and retain qualified scientific and technical personnel, consultants and advisors. We are highly dependent on the principal members of our scientific and management staff. The long-term loss of services of key executives might significantly delay or prevent the achievement of our research, development, and business objectives. We do not maintain key-man life insurance with respect to any of our employees, nor do we intend to secure such insurance.

We will need to recruit additional personnel in order to achieve our operating goals. In order to pursue product development and marketing and sales activities, if any, we will need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales. We also rely on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on acceptable terms, if at all. Additionally, our most significant facility is located in Iowa, which may make attracting and retaining qualified scientific and technical personnel from outside of Iowa difficult. The failure to attract and retain qualified personnel, consultants and advisors could have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to Manufacturing Activities

We rely on third-party manufacturers to produce our preclinical and clinical product candidate supplies and we intend to rely on third parties to produce commercial supplies of any product candidates that may be approved in the future. Any failure by a third-party manufacturer to produce supplies for us may delay or impair our ability to complete our clinical trials or commercialize our product candidates.

We do not possess all of the capabilities to fully commercialize any of our product candidates on our own. If we are unable to arrange for third-party manufacturing sources or to do so on commercially reasonable terms, we may not be able to complete development of such product candidates or market them. In addition, we currently rely on our partner Merck for the supply of our Ebola vaccine product candidate and other third party manufacturers for our supply of indoximod, NLG802, NLG207, and NLG919 for preclinical and clinical studies. Problems with any of our facilities or processes, or our contract manufacturers' facilities or processes, could prevent or delay the production of adequate supplies of indoximod, NLG802, NLG207, NLG919, our Ebola vaccine product candidate or other finished products.

Any prolonged delay or interruption in the operations of our current or future contract manufacturers' facilities could result in cancellation of shipments, loss of components in the process of being manufactured or a shortfall in the availability of a product. A number of factors could cause interruptions, including the inability of a supplier to

provide raw materials, equipment malfunctions or failures, damage to a facility due to natural disasters, changes in international or U.S. regulatory requirements or standards that require modifications to our manufacturing processes, action by regulatory authorities or by us that results in the halting or slowdown of production of components or finished product due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified production capacity and sufficiently trained or qualified personnel may not be available on a timely or cost-effective basis or at all. Difficulties or delays in our contract manufacturers' production of product candidates could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue and market share if we are unable to meet market demand for any products that are approved for sale on a timely basis.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, failure of the third party to accept orders for supply of drug substance or drug product and the possibility of termination or nonrenewal of the agreement by the third-party based on its own business priorities and at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes as needed, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates that may have been granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture our product candidates. Such suppliers may not sell this capital equipment or these raw materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of this capital equipment or these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Because of the complex nature of many of our early-stage compounds and product candidates, our manufacturers may not be able to manufacture such compounds and product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize related products. If we successfully commercialize any of our product candidates, we may be required to establish or access large-scale commercial manufacturing capabilities. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. To meet our projected needs for commercial manufacturing in the event that one or more of our product candidates gains marketing approval, third parties with whom we currently work will need to increase their scale of production or we will need to secure alternate suppliers.

Furthermore, we do not currently have experience with the management of relationships related to commercial-scale contract manufacturing, and we may incur substantial costs to develop the capability to negotiate and enter into relationships with third-party contract manufacturers.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our products.

All entities involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our Company, our existing contract manufacturers and those we may engage in the future, and Merck in its capacity as our licensee, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP regulations. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and

products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of any of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. In addition, to the extent that we rely on foreign contract manufacturers, as we do currently for our Ebola vaccine product candidate, we are or will be subject to additional risks including the need to comply with export and import regulations.

If our current or future contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

Our facility is located in areas where floods and tornados are known to occur, and the occurrence of a flood, tornado or other catastrophic disaster could damage our facilities and equipment, which could cause us to curtail or cease operations.

Our primary facility is located in Ames, Iowa, which is susceptible to floods and tornados, and our facility is therefore vulnerable to damage or disruption from floods and tornados. We are also vulnerable to damage from other types of disasters, such as power loss, fire and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We currently carry business insurance (real, personal and business income) of nearly $11.6 million in the aggregate, but this policy does not cover disasters such as floods and earthquakes. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our information technology infrastructure, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber-attacks. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent the adverse effect of such events. Significant disruptions of our information technology systems or breaches of data security could adversely affect our business.

Risks Relating to Regulation of Our Industry

The industry within which we operate and our business are subject to extensive regulation, which is costly and time-consuming and which may subject us to unanticipated delays.

The research, development, testing, manufacturing, labeling, packaging, marketing, distribution, promotion and advertising of biologic and pharmaceutical products such as our product candidates are subject to extensive regulation by governmental regulatory authorities in the United States and other countries. The drug development and approval process is generally lengthy, expensive and subject to unanticipated delays. Data obtained from preclinical and clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. In addition,

delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of development and regulatory review of each submitted application for approval. To obtain approval for a product candidate, we must demonstrate to the satisfaction of the regulatory authorities that the product candidate is safe and effective in the case of a small-molecule pharmaceutical product, or is safe, pure and potent in the case of a biologic, which typically takes several years or more depending upon the type, complexity and novelty of the product and requires the expenditure of substantial resources.

There can be no assurance that we will not encounter problems in clinical trials that would cause us or the regulatory authorities to delay or suspend clinical trials. Any such delay or suspension could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that we will not encounter problems in clinical trials that would cause us or the regulatory authorities to delay or suspend clinical trials. Any such delay or suspension could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that clinical trials for any of our product candidates currently under development will be completed successfully or within any specified time period, if at all. Further, there can also be no assurance that such testing will show any product to be safe, pure, potent or effective. We cannot predict when, if ever, we might submit for regulatory review our product candidates currently under development. In addition, regardless of how much time and resources we devote to the development of a product candidate, there can be no assurance that regulatory approval will be obtained for that product candidate.

Even if such regulatory approval is obtained, we, our products and any contract manufacturers or commercial collaborators of ours will be subject to continual regulatory review in both the United States and other countries. Later discovery of previously unknown problems with regard to a product, distributor or manufacturer may result in restrictions, including withdrawal of the product from the market and/or disqualification or decertification of the distributor or manufacturer. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- warning letters;
- civil or criminal penalties;
- injunctions;
- suspension of or withdrawal of regulatory approval;
- total or partial suspension of any ongoing clinical trials or of production;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of new biologic and pharmaceutical products through lengthy and detailed preclinical and clinical testing procedures, sampling activities and other costly and time-consuming compliance procedures. Clinical trials are vigorously regulated and must meet requirements for FDA review and oversight and requirements under GCP guidelines. A new drug may not be marketed in the United States until the FDA has approved it. There can be no assurance that we will not encounter delays or rejections or that the FDA will not make policy changes during the period of product development and FDA regulatory review of each submitted biologics license application (BLA) and new drug application (NDA). A delay in obtaining, or failure to obtain, such approvals would have a material adverse effect on our business, financial condition and results of operations. Even if regulatory approval were obtained, it would be limited as to the indicated uses for which the product may be promoted or marketed. A marketed product, its manufacturer and the facilities in which it is manufactured are subject to continual review and periodic inspections. If marketing approval is granted, we would be required to comply with FDA requirements for manufacturing, labeling, advertising, record-keeping and reporting of adverse experiences and other information. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label, although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications. Companies may

also share truthful and not misleading information that is otherwise consistent with the labeling. In addition, we would be required to continue to comply with federal and state anti-kickback and other healthcare fraud and abuse laws that pertain to the marketing of pharmaceuticals, among other things. Failure to comply with regulatory requirements and other factors could subject us to regulatory or judicial enforcement actions, including product recalls or seizures, injunctions, withdrawal of the product from the market, civil penalties, criminal prosecution, refusals to approve new products and withdrawals of existing approvals, as well as enhanced product liability exposure, any of which could have a material adverse effect on our business, financial condition and results of operations. Sales of our products outside the United States will be subject to foreign regulatory requirements governing clinical trials, marketing approval, manufacturing and pricing. Noncompliance with these requirements could result in enforcement actions or penalties or could delay the introduction of our products in certain countries.

The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement outside the United States vary greatly from country to country. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Foreign regulatory authorities could also require additional testing. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our products and may have a material adverse effect on our results of operations and financial condition.

We are also subject to laws generally applicable to businesses including, but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistleblowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistleblowing claim, even if without merit, could result in costly litigation or regulatory action or otherwise harm our business, results of operations, financial condition, cash flow and future prospects.

The availability of coverage and amount of reimbursement for our product candidates, if approved, and the manner in which government and private payers may reimburse for our potential products, are uncertain.

In both the United States and foreign markets, sales of our proposed products will depend in part on the availability of coverage and reimbursement from third-party payers such as government health administration authorities, private health insurers and other organizations. In addition, the process for determining whether a third party payor will provide coverage for a pharmaceutical typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payer will pay for the product once coverage is approved. Third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. There can be no assurance that our proposed products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Our future levels of revenues and profitability may be affected by the continuing efforts of governmental and third-party payers to contain or reduce the costs of healthcare. We cannot predict the effect that private sector or governmental health care reforms may have on our business, and there can be no assurance that any such reforms will not have a material adverse effect on our business, financial condition and results of operations. Legislation and regulations affecting the pricing of pharmaceuticals may change before any of our proposed products are approved for marketing. Adoption of such legislation could further limit reimbursement for medical products and services. As a result, we may elect not to market future products in certain markets.

Moreover, while we are in clinical trials, we will not be reimbursed for any of our materials used during the clinical trials, however, certain services rendered to clinical trial participants may be reimbursable by third-party payors for standard of care treatment if not otherwise reimbursed under the applicable clinical trial study budget.

The biopharmaceutical industry is subject to significant regulation and oversight in the United States, in addition to approval of products for sale and marketing; our failure to comply with these laws could harm our results of operations and financial condition.

In addition to FDA restrictions on marketing of biopharmaceutical products, our operations may be directly, or indirectly through our relationships with healthcare providers, customers and third-party payers, subject to various

federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute. These laws may impact, among other things, our proposed sales, and education programs, and these laws have been applied to restrict certain marketing practices in the biopharmaceutical industry. In addition, we may be subject to patient privacy regulation by both the U.S. federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, among others, the following:

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.
- The federal civil False Claims Act prohibits any person or entity from knowingly presenting, or causing to be presented, to the federal government a claim for payment or approval that is false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Several pharmaceutical and other health-care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of off-label promotion. Private parties may initiate qui tam whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit.
- The federal Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA), imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their implementing regulations imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization on covered entities, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information.
- The federal Food, Drug and Cosmetic Act (FDCA) prohibits, among other things, the adulteration or misbranding of drugs and medical devices.
- The federal Physician Payments Sunshine Act, and its implementing regulations require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services (CMS), information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members.
- Analogous state laws and regulations include: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer,

including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information and that require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. It is possible that some of our business activities could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business, financial condition and results of operations.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that required that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order included a budget neutrality provision that required the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations that can be repealed to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the United States Office of Management and Budget on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. Further, on February 24, 2017, President Trump issued an Executive Order requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification. It is difficult to predict how these requirements will continue to be enforced, the extent to which they will continue to impact the FDA's ability to exercise its regulatory authority, and the negative impact they may have on our business.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The U.S. and some foreign jurisdictions are considering or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, in the United States, the pharmaceutical industry has been affected by the passage of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the ACA), which, among other things, imposed new fees on entities that manufacture or import certain branded prescription drugs and expanded pharmaceutical manufacturer obligations to provide discounts and rebates to certain government programs. There have been judicial and congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for

health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (the BBA) among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Although the Texas U.S. District Court Judge, as well as the presidential administration and CMS have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, there has been particular and increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices in recent years, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. There have been several recent U.S. Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2018, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the "Wholesale Acquisition Cost", or list price, of that drug or biological product. Any of these initiatives could harm our ability to generate revenues.

In the future, there will likely continue to be proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of drug products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Individual states are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payers or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding

procedures to determine which pharmaceutical products and suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last 10 years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (the Right to Try Act) was signed into law. The law, among other things, provides a federal framework for certain patients to access certain IND products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislative or administrative action, either in the United States or abroad.

We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

Our research and development involves the controlled use of hazardous materials, chemicals, various active microorganisms and volatile organic compounds, and we may incur significant costs as a result of the need to comply with numerous laws and regulations. We are subject to laws and regulations enforced by the FDA, the Drug Enforcement Agency, foreign health authorities and other regulatory requirements, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Food, Drug and Cosmetic Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of our products, materials used to develop and manufacture our product candidates, and resulting waste products. Although we believe that our safety procedures for handling and disposing of such materials, and for killing any unused microorganisms before disposing of them, comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Failure to comply with existing or future data protection laws and regulations related to privacy or data security could lead to government enforcement actions (which could include civil or criminal fines or penalties), private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

Regulation of data processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. We and our partners may be subject to current, new, or modified federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our partners to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our partners' ability to process or use data in order to support the provision of our products or services, or affect our or our partners' ability to offer our products and services in certain locations.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other

personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to civil and/or criminal penalties including if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including, without limitation, the European Union Directive 95/46/EC (the Directive), and the European Union's General Data Protection Regulation (the GDPR) that took effect in May 2018, and member state data protection legislation, may also apply to health-related and other personal information obtained outside of the United States. These laws impose strict obligations on the ability to process health-related and other personal information of data subjects in the European Union, including in relation to use, collection, analysis and transfer of such personal information. These laws include several requirements relating to the consent of the individuals to whom the personal data relates, limitations on data processing, establishing a legal basis for processing, notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, the security and confidentiality of the personal data and various rights that data subjects may exercise.

The Directive and the GDPR prohibits, without an appropriate legal basis, the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions.

Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with European Union data protection laws remains. For example, ongoing legal challenges in Europe to the mechanisms allowing companies to transfer personal data from the EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers, such as the European Union-U.S. and Swiss-U.S. Privacy Shield framework. Additionally, other countries have passed or are considering passing laws requiring local data residency.

Under the GDPR, regulators may impose substantial fines and penalties for non-compliance. Companies that violate the GDPR can face fines of up to the greater of 20 million Euros or 4% of their worldwide annual turnover (revenue). The GDPR has increased our responsibility and liability in relation to personal data that we process, requiring us to put in place additional mechanisms to ensure compliance with the GDPR and other EU and international data protection rules.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations related to security or privacy, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Compliance with data protection laws may be time-consuming, require additional resources and could result in increased expenses, reduce overall demand for our products and services and make it more difficult to meet expectations of our commitments to customers or partners.

Any of these matters could materially adversely affect our business, financial condition, or operational results.

Financial Risks

We have a history of net losses. We incurred a net loss for the years ended December 31, 2016, 2017 and 2018 and expect to continue to incur net losses for the foreseeable future, and we may never achieve or maintain profitability in the future.

We were profitable in the year ended December 31, 2014, primarily as a result of upfront payments under the Genentech Agreement and the Merck Agreement. We are not entitled to receive any additional upfront payments under these licensing or collaboration agreements. We do not expect any milestone or royalty payments under these

or other agreements, if any, to be sufficient to make us profitable in future years. We incurred a loss of $10.0 million for the three months ended March 31, 2019 and we do not expect to be profitable for the foreseeable future. We anticipate that we will continue to incur operating losses over the next several years as we continue our clinical development programs.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities, government grants, economic development loans and capital lease and equipment financing. The size of our future net losses will depend, in part, on the rate of growth or contraction of our expenses and the level and rate of growth, if any, of our revenues. Our ability to achieve profitability in future years is dependent on our ability, alone or with others, to complete the development of our products successfully, obtain the required regulatory approvals, manufacture and market our proposed products successfully or have such products manufactured and marketed by others and gain market acceptance for such products. There can be no assurance as to whether or when we will achieve profitability.

We may require substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

Development of our product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution capabilities, either internally or through collaborations with third parties. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings (including FDA review of any BLA or NDA we file);
- payments required with respect to development milestones we achieve under our in-licensing agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the costs associated with commercializing our product candidates, if they receive regulatory approval;
- the cost of manufacturing our product candidates and any products we commercialize;
- the cost and timing of developing our ability to establish sales and marketing capabilities;
- the potential requirement to repay our outstanding government provided loans;
- competing technological efforts and market developments;
- changes in our existing research relationships;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing and receipt of revenues from existing or future products, if any; and
- payments received under any future strategic collaborations.

We anticipate that we will continue to generate significant losses in the future as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates. We believe that our existing cash and cash equivalents will allow us to fund our operating plan in the near and medium term. However, our operating plan may change as a result of factors currently unknown to us.

There can be no assurance that our revenue and expense forecasts will prove to be accurate, and any change in the foregoing assumptions could require us to obtain additional financing earlier than anticipated. There is a risk of

delay or failure at any stage of developing a product candidate, and the time required and costs involved in successfully accomplishing our objectives cannot be accurately predicted. Actual drug research and development costs could substantially exceed budgeted amounts, which could force us to delay, reduce the scope of or eliminate one or more of our research or development programs.

We are party to license agreements with various parties pursuant to which we have obtained licenses to certain patents, patent applications and other intellectual property related to our product candidates and product development efforts. We are obligated to make aggregate payments ranging from approximately $250,000 to $2.8 million under our license agreements (and in some cases, for each product candidate in such license) upon achievement of development and regulatory approval milestones specified in the applicable license. The timing of our achievement of these events and corresponding milestone payments to our licensors is subject to factors relating to the clinical and regulatory development and commercialization of our product candidates, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization or marketing efforts or seek funds to meet these obligations on terms unfavorable to us.

We may never be able to generate a sufficient amount of product revenue to cover our expenses. Until we do, we expect to seek additional funding through public or private equity or debt financings, collaborative relationships, capital lease transactions or other available financing transactions. However, there can be no assurance that additional financing will be available on acceptable terms, if at all, and such financings could be dilutive to existing stockholders. Moreover, in the event that additional funds are obtained through arrangements with collaborators, such arrangements may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs. Our failure to obtain adequate financing when needed and on acceptable terms would have a material adverse effect on our business, financial condition and results of operations.

Even though we have received governmental support in the past, we may not continue to receive support at the same level or at all.

We have received significant financial assistance, primarily in the form of forgivable loans, from state and local governments. We have also received significant financial assistance, primarily in the form of grants and contracts, from federal agencies to support our infectious disease research. There can be no assurance that we will continue to receive the same level of assistance from these or other government agencies, if at all.

Through our subsidiary, BPS, we have received funding from multiple government agencies for our Ebola vaccine product candidate development efforts. There is no guarantee that we will receive sufficient, or any, future grant funding to meet our obligations related to our Ebola vaccine development or that we or Merck will succeed in developing an Ebola vaccine. The termination of a United States government grant, contract or relationship as a result of our failure to satisfy any of our obligations under the grants or contracts would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, there can be no assurance that we will secure comparable contracts with, or grants from, the United States government in the future.

Changes in our effective income tax rate could adversely affect our results of operations in the future.

For the three months ended March 31, 2019 we have no income tax benefit or expense. Our effective income tax rate, as well as our relative domestic and international tax liabilities, will depend in part on the allocation of any future income among different jurisdictions. In addition, various factors may have favorable or unfavorable effects on our effective income tax rate in individual jurisdictions or in the aggregate. These factors include whether tax authorities agree with our interpretations of existing tax laws, any required accounting for stock options and other share-based compensation, changes in tax laws and rates (including the recently enacted U.S. federal income tax law changes), our future levels of research and development spending, changes in accounting standards, changes in the mix of any future earnings in the various tax jurisdictions in which we may operate, the outcome of any examinations by the U.S. Internal Revenue Service or other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings. The effect on our income tax liabilities resulting from the above-mentioned factors or other factors could have a material adverse effect on our results of operations.

The comprehensive tax reform bill of 2017 could adversely affect our business and financial condition.

On December 22, 2017 the Tax Act was signed into law. The Tax Act significantly revised the Internal Revenue Code of 1986, as amended (the Code) and included, among other things, significant changes to corporate taxation, including a reduction of the corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income for net operating losses arising in taxable years beginning after December 31, 2017 and elimination of net operating loss carrybacks for net operating losses arising in taxable years beginning after December 31, 2017, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act did not have a material impact on our business. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to the Tax Act and the potential tax consequences of investing in or holding our common stock.

Risks Relating to Competition

We compete in an industry characterized by extensive research and development efforts and rapid technological progress. New discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive.

New developments occur and are expected to continue to occur at a rapid pace, and there can be no assurance that discoveries or commercial developments by our competitors will not render some or all of our potential products obsolete or non-competitive, which would have a material adverse effect on our business, financial condition and results of operations.

We expect to compete with fully integrated and well-established pharmaceutical and biotechnology companies in the near and long term. Most of these companies have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. Such companies may succeed in discovering and developing pharmaceutical products more rapidly than we do or pharmaceutical products that are safer, more effective or less costly than any that we may develop. Such companies also may be more successful than we are in production and marketing. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations also conduct clinical trials, seek patent protection and establish collaborative arrangements for the development of oncology products.

We may face competition based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, reimbursement coverage, price and patent position. There can be no assurance that our competitors will not develop safer and more effective products, commercialize products earlier than we do, or obtain patent protection or intellectual property rights that limit our ability to commercialize our products.

There can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide us with proprietary protection or a competitive advantage.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Many of the products that we are attempting to develop and commercialize will be competing with existing therapies. In addition, a number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies both in the United States and abroad. Our competitors may utilize discovery technologies and techniques or collaborate with third parties in order to develop products more rapidly or successfully than we or our collaborators are able to do. Many of our competitors, particularly large pharmaceutical companies, have

substantially greater financial, technical and human resources than we do. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors.

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies, firms specialized in the development and production of vaccines, checkpoint inhibitors, and other immunotherapies, and major universities and research institutions. Many companies have entered into the field of immuno-oncology and are developing or commercializing products in areas that we have targeted for product development. Some of these products use therapeutic approaches that may compete directly with our product candidates. Most of our competitors possess substantially greater financial, technical and human resources than we possess. In addition, many of our competitors have significantly greater experience than we have in conducting preclinical and nonclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of drugs and manufacturing facilities. Accordingly, our competitors may succeed in obtaining regulatory approval for drugs more rapidly than we do. We expect to face growing competition for enrollment of patients in our clinical trials, which could delay or adversely affect our ability to complete such trials. We may also be adversely affected by the clinical trial results of our competitors. For example, if a competitor announces inconclusive or negative clinical trial results with respect to an IDO pathway inhibitor, expectations about IDO pathway inhibitors may be generally impacted and we may experience difficulty in enrolling patients in our indoximod trials. If we obtain regulatory approval and launch commercial sales of our product candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

We also face competition from pharmaceutical and biotechnology companies, academic institutions, government agencies and private research organizations in recruiting and retaining highly qualified scientific personnel and consultants and in the development and acquisition of technologies. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, thereby preventing us from obtaining technology on commercially reasonable terms, if at all. We will also compete for the services of third parties that may have already developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies to target the diseases on which we have focused both inside and outside of the United States.

Our competitive position will also depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often lengthy period between technological conception and commercial sales. We will require substantial capital resources to complete development of some or all of our products, obtain the necessary regulatory approvals and successfully manufacture and market our products. In order to secure capital resources, we may elect to sell additional capital stock, which would dilute the holdings of existing stockholders. We may also attempt to obtain funds through research grants and agreements with commercial collaborators. However, these types of financings are uncertain because they are at the discretion of the organizations and companies that control the funds. Accordingly, we may not receive any additional funds from grants or collaborations.

Research and discoveries by others may result in breakthroughs that render indoximod, NLG802, NLG207, and NLG919 product candidates, or our other potential products obsolete even before they begin to generate any revenue. If the FDA approves the commercial sale of any of our product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited or no experience. We expect that competition among products approved for sale will be based, among other things, on product efficacy, price, safety, reliability, availability, patent protection, and sales, marketing and distribution capabilities. Our profitability and financial position will suffer if our products receive regulatory approval but cannot compete effectively in the marketplace.

Our future products, if any, may not be accepted in the marketplace and therefore, we may not be able to generate significant revenue, or any revenue.

Even if our potential products are approved for sale, physicians and the medical community may not ultimately use them or may use them only in applications more restricted than we expect. Our future products, if successfully developed, will compete with a number of traditional immuno-oncology products manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products will also compete with new products currently under development by such companies and others. Physicians will prescribe a product only if they

determine, based on experience, clinical data, side effect profiles and other factors, that it is beneficial as compared to other products currently in use. Many other factors influence the adoption of new products, including marketing and distribution restrictions, course of treatment, adverse publicity, product pricing, the views of thought leaders in the medical community and coverage and adequate reimbursement by government and private third-party payers.

Risks Relating to Our Arrangements with Third Parties

We rely on third parties to conduct our preclinical studies and our clinical trials. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for our product candidates, or we may be delayed in doing so.

We do not have the ability to conduct preclinical studies or clinical trials independently for our product candidates. We must rely on third parties, such as contract research organizations, medical institutions, academic institutions, clinical investigators and contract laboratories, as well as our strategic collaborators and the third parties that they may use, to conduct our preclinical studies and clinical trials. Other than to the extent that Merck is responsible for clinical trials of our Ebola vaccine product candidate, we are responsible for confirming that our studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with GLP for conducting and recording the results of our preclinical studies and with GCP for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with GCP, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be more costly than expected or budgeted, be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or to commercialize the product candidate being tested in such trials, or may be delayed in doing so.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

We are also dependent on Merck for the development of the product candidates that are the subject of the Merck Agreement. If the company does not succeed in advancing the product candidate to final approval, or decides to discontinue its collaboration with us, such failure or decision, could materially harm our business.

If we fail to enter into any needed collaboration agreements for our product candidates, or if we enter into collaborations that are ultimately unsuccessful, we may be unable to commercialize any potential product effectively or at all.

To successfully commercialize any potential product, we will need substantial financial resources as well as expertise and physical resources and systems. We may elect to develop some or all of these physical resources and systems and expertise ourselves or we may seek to collaborate with another company that can provide some or all of such physical resources and systems as well as financial resources and expertise, as we did in the case of the Genentech Agreement and the Merck Agreement. Such collaborations are complex, and any potential discussions may not result in a definitive agreement for many reasons. For example, whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator’s evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the potential market for the subject product candidates, the costs and complexities of manufacturing and delivering the potential product to patients, the potential of competing products, the existence of uncertainty with respect to ownership or the coverage of our technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. If we were to determine that a collaboration for a potential product is necessary or beneficial and were unable to enter into such a collaboration on acceptable terms, we might elect to delay or scale back the commercialization of the potential product in order to preserve our financial resources or to allow us adequate time to develop the required physical resources and systems and expertise ourselves.

If we enter into a collaboration agreement we consider acceptable, including the Merck Agreement to develop and commercialize our Ebola vaccine product candidate, the collaboration may not proceed as quickly, smoothly or successfully as we plan. The risks in a collaboration agreement include the following:

- the collaborator may not apply the expected financial resources, efforts or required expertise in developing the physical resources and systems necessary to successfully commercialize the subject potential product;
- the collaborator may not invest in the development of a sales and marketing force and the related infrastructure at levels that ensure that sales of the potential product reach their full potential;
- disputes may arise between us and a collaborator that delay the commercialization or adversely affect its sales or profitability of the potential product; or
- the collaborator may independently develop, or develop with third parties, products that could compete with the potential product.

Under the Merck Agreement and any other collaboration for our product candidates, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates, and such disputes may be difficult and costly to resolve or may not be resolved. In addition, a collaborator for the potential product may have the right to terminate the collaboration at its discretion, or to discontinue development of a particular product candidate. For example, in June 2017, Genentech gave notice that it was terminating the Genentech Agreement with respect to NLG919 and gave notice in May 2018 that the remainder of the Agreement would terminate no later than November 6, 2018. Further, Merck has the right to terminate the Merck Agreement for any reason after a specified advance notice period. Any termination may require us to seek a new collaborator, which we may not be able to do on a timely basis, if at all, or may require us to delay or scale back the development or commercialization efforts. The occurrence of any of these events could adversely affect the development or commercialization of the potential product and materially harm our business and stock price by delaying the sale of any product that may be approved by the FDA in the future, by slowing the growth of such sales, by reducing the profitability of the product and/or by adversely affecting the reputation of the product.

We may explore strategic collaborations that may never materialize or may fail.

We may, in the future, periodically explore a variety of possible strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in the process of seeking appropriate strategic collaborators, and such collaborations can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

We are required under the Merck Agreement, and we may be required under other collaborations, to relinquish important rights to and control over the development of our product candidates to our collaborators or otherwise be subject to unfavorable terms.

Our collaborations, including any future strategic collaborations we enter into, could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- other than under the Merck Agreement, we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;

- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may also adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Risks Relating to Protecting Our Intellectual Property

If we are unable to protect our proprietary rights or to defend against infringement claims, we may not be able to compete effectively or operate profitably.

Our success will depend, in part, on our ability to obtain patents, operate without infringing the proprietary rights of others and maintain trade secrets, both in the United States and other countries. Patent matters in the biotechnology and pharmaceutical industries can be highly uncertain and involve complex legal and factual questions. Accordingly, the validity, breadth, and enforceability of our patents and the existence of potentially blocking patent rights of others cannot be predicted, either in the United States or in other countries.

There can be no assurance that we will discover or develop patentable products or processes, or that patents will issue from any of the currently pending patent applications or that claims granted on issued patents will be sufficient to protect our technology or adequately cover the products we may actually sell. Potential competitors or other researchers in the field may have filed patent applications, been issued patents, published articles or otherwise created prior art that could restrict or block our efforts to obtain additional patents. There also can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated, rendered unenforceable or circumvented or that the rights granted thereunder will provide us with proprietary protection or competitive advantages. Our patent rights also depend on our compliance with technology and patent licenses upon which our patent rights are based and upon the validity of assignments of patent rights from consultants and other inventors that were, or are, not employed by us.

In addition, competitors may manufacture and sell our potential products in those foreign countries where we have not filed for patent protection or where patent protection may be unavailable, not obtainable or ultimately not enforceable. In addition, even where patent protection is obtained, third-party competitors may challenge our patent claims in the various patent offices, for example via opposition in the European Patent Office or reexamination or interference proceedings in the United States Patent and Trademark Office (USPTO). The ability of such competitors to sell such products in the United States or in foreign countries where we have obtained patents is usually governed by the patent laws of the countries in which the product is sold.

Merck, which has sublicensed our Ebola vaccine product candidate, has received correspondence from Yale University asserting that it owns certain intellectual property rights with respect to the Ebola vaccine that they assert,

among other things, may need to be licensed by Merck. We also received correspondence from Yale University relating to the research and construction of the Ebola vaccine product by our licensor PHAC. If Merck were required to pay royalties to Yale University, that could result in a reduction of Merck's royalty obligations to us. If Merck otherwise suffered damages as a result of claims by Yale University, it is possible that Merck could seek indemnification from us.

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair our ability to access additional capital and/or cost us significant funds to defend.

We intend to rely on patent rights for our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets.

We rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain regulatory exclusivity and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technologies and product candidates.

We have sought to protect our proprietary position by filing patent applications related to our technologies and product candidates that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable, or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection or data exclusivity, for our product candidates, we may not be able to compete effectively, and our business and results of operations would be harmed.

We may not have sufficient patent term protections for our product candidates to effectively protect our business.

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Additional patent terms may be available through a patent term adjustment process, resulting from the USPTO delays during prosecution. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from generic medications.

Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data exclusivity terms of our product candidates. We

will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our product candidates for an extended period after regulatory approval, if any, which would negatively impact our business, financial condition, results of operations, and prospects. If we do not have sufficient patent terms or regulatory exclusivity to protect our product candidates, our business and results of operations will be adversely affected.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office has developed regulations and procedures to govern administration of the Leahy-Smith Act, but many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first-inventor-to-file provisions, only became effective 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We may be subject to litigation with respect to the ownership and use of intellectual property that will be costly to defend or pursue and uncertain in its outcome.

Our success also will depend, in part, on our refraining from infringing patents or otherwise violating intellectual property owned or controlled by others. Pharmaceutical companies, biotechnology companies, universities, research institutions, and others may have filed patent applications or have received, or may obtain, issued patents in the United States or elsewhere relating to aspects of our technology. It is uncertain whether the issuance of any third-party patents will require us to alter our products or processes, obtain licenses, or cease certain activities. Some third-party applications or patents may conflict with our issued patents or pending applications. Any such conflict could result in a significant reduction of the scope or value of our issued or licensed patents.

In addition, if patents issued to other companies contain blocking, dominating or conflicting claims and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative non-infringing technology and cease practicing those activities, including potentially manufacturing or selling any products deemed to infringe those patents. If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from pursuing the development and commercialization of certain of our potential products. Our failure to obtain a license to any technology that we may require to commercialize our products on favorable terms may have a material adverse impact on our business, financial condition and results of operations.

Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of the proprietary rights of others. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any third party would be found to infringe our patents.

In addition, if our competitors filed patent applications in the United States that claim technology also claimed by us, and such applications were filed before the Leahy-Smith Act took effect, we may have to participate in interference proceedings to determine priority of invention. These proceedings, if initiated by the USPTO, could result in substantial cost to us, even if the eventual outcome is favorable to us. Such proceedings can be lengthy; are costly to defend and involve complex questions of law and fact, the outcomes of which are difficult to predict. An adverse outcome with respect to a third party claim or in an interference proceeding could subject us to significant liabilities, require us to license disputed rights from third parties, or require us to cease using such technology, any of which could have a material adverse effect on our business, financial condition and results of operations.

We also rely on trade secrets to protect technology, especially where patent protection is not believed to be appropriate or obtainable or where patents have not issued. We attempt to protect our proprietary technology and processes, in part, with confidentiality agreements and assignment of invention agreements with our employees and confidentiality agreements with our consultants and certain contractors. There can be no assurance that these

agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We may fail in certain circumstances to obtain the necessary confidentiality agreements, or their scope or term may not be sufficiently broad to protect our interests.

If our trade secrets or other intellectual property becomes known to our competitors, it could result in a material adverse effect on our business, financial condition and results of operations. To the extent that we or our consultants or research collaborators use intellectual property owned by others in work for us, disputes may also arise as to the rights to related or resulting know-how and inventions.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States.

These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries, particularly some developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Relating to Our Exposure to Litigation

We are exposed to potential product liability or similar claims, and insurance against these claims may not be available to us at a reasonable rate in the future.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and commercial sale of human therapeutic products. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper administration of the product candidate, or other factors. Many of these patients are already seriously ill and are therefore particularly vulnerable to further illness or death. In addition, healthy volunteers in our indoximod clinical trial or our Ebola vaccine product candidate clinical trial may suffer, or perceive themselves to suffer, personal injury or death related to the Ebola vaccine product candidates and may initiate legal action against us.

We currently carry clinical trial liability insurance in the amount of $5.0 million in the aggregate for claims related to our product candidates other than our Ebola vaccine product candidate. We currently carry clinical trial liability insurance in the amount of $10.0 million in the aggregate for claims related to our Ebola vaccine product candidate. We additionally currently carry clinical trial coverage in lower aggregate amounts in local markets where our clinical trials are conducted on a selective, trial by trial basis. There can be no assurance that we will be able to maintain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance. In addition, there can be no

assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any future products by us or our collaborators.

On December 9, 2014, the HHS declared our Ebola vaccine product candidate covered under the Public Readiness and Emergency Preparedness Act. This declaration provides immunity under U.S. law against legal claims related to the manufacturing, testing, development, distribution and administration of our vaccine candidate. It does not generally provide immunity for a claim brought in a court outside the United States.

Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

We are involved in a securities class-action litigation and are at risk of additional similar litigation in the future that could divert management's attention and adversely affect our business and could subject us to significant liabilities.

In the past, securities class action litigation has often been brought against a company following periods of volatility in the market price of securities. We are a party to the securities class action litigation described in Part II, Item 1 of this Quarterly Report on Form 10-Q under the heading "Legal Proceedings." The defense of this litigation may increase our expenses and divert our management's attention and resources and any unfavorable outcome could have a material adverse effect on our business and results of operations. Any adverse determination in this litigation, or any amounts paid to settle this litigation could require that we make significant payments. In addition, we may in the future be the target of other securities class actions or similar litigation.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and could decline significantly.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including those described elsewhere in this "Risk Factors" section of this Quarterly Report on Form 10-Q and the following:

- new products, product candidates or new uses for existing products introduced or announced by our strategic collaborators, or our competitors, and the timing of these introductions or announcements;
- actual or anticipated results from and any delays in our clinical trials, as well as results of regulatory reviews relating to the approval of our product candidates;
- variations in the level of expenses related to any of our product candidates or clinical development programs, including those relating to the timing of invoices from, and other billing practices of, our clinical research organizations and clinical trial sites;
- expenses related to, or our ability or perceived ability to secure, an adequate supply of any future products approved for commercial sale;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures and capital commitments;

- the commercial or clinical success or failure, or perceived success or failure, of our collaborators, including Merck;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- media attention, or changes in media attention, given to cancer and cancer treatment, the recent Ebola epidemic and efforts to develop treatments and vaccines for Ebola, or any other condition or disease that our product candidates are being developed to treat;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- the financial projections we may provide to the public, and any changes in these projections or our failure to meet these projections;
- deviations from securities analysts' estimates or the impact of other analyst rating downgrades by any securities analysts who follow our common stock;
- other events or factors, including those resulting from political uncertainty, war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. We are currently party to the securities class action litigation described in Part II, Item 1 of this Quarterly Report on Form 10-Q under the heading "Legal Proceedings." This litigation and others like it that could be brought against us in the future could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of March 31, 2019, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 40.7% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after March 31, 2019. These stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our Board of Directors, future issuances of our common stock or other securities, declarations of dividends on our common stock and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock. In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares may be distributed and subsequently voted.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to meet compliance obligations.

As a public company, we incur significant legal, accounting and other expenses to comply with reporting requirements of the Securities Exchange Act of 1934 (the Exchange Act), the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), as well as rules subsequently implemented by the SEC and The Nasdaq Global Market. Meeting the requirements of these rules and regulations entails significant legal and financial compliance costs, makes some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel devote a substantial amount of time to these compliance requirements. In addition, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to publish a report by our management on our internal control over financial reporting. To achieve compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which has been both costly and challenging. To maintain compliance on an ongoing basis, we will need to dedicate internal resources, engage outside consultants and adopt a detailed work plan. Despite our effort, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We do not expect to pay any cash dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking only cash dividends should not purchase our common stock.

Provisions in our certificate of incorporation, our by-laws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our certificate of incorporation, our by-laws or Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. These provisions include:

- the division of our Board of Directors into three classes with staggered, three-year terms;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to call special meetings;
- limitations on the ability of stockholders to remove directors or amend our by-laws; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person that together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

The holdings of our stockholders may be diluted, and the prices of our securities may decrease, by the exercise of outstanding stock options or by future issuances of securities by us.

We may issue additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock or the exercise of stock options would dilute existing investors and could adversely affect the price of our securities. In addition, such securities may have rights senior to the rights of securities held by existing investors.

Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Code.

Sections 382 and 383 of the Code limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. A Section 382 ownership change can, therefore, result in significantly greater tax liabilities than a corporation would incur in the absence of such a change, and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

Based on Section 382 ownership change analyses, we believe that, from our inception through December 31, 2017, we experienced Section 382 ownership changes in September 2001 and March 2003, and BPS experienced Section 382 ownership changes in January 2006 and January 2011. These ownership changes limited our ability to utilize federal net operating loss carryforwards and certain other tax attributes that accrued prior to the respective ownership changes of us and our subsidiaries and may continue to limit our ability to utilize such attributes in the future.

Additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders.

Accounting pronouncements may impact our reported results of operations and financial position.

U.S. GAAP and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new pronouncements or the application of existing pronouncements to changes in our business could significantly alter our reported financial statements and results of operations.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following exhibits are filed with this Form 10-Q or incorporated herein by reference to the document set forth next to the exhibit listed below. Where so indicated, exhibits that were previously filed are incorporated by reference.

Exhibit Number	Description	Incorporated By Reference			Filed Herewith
		Form	Filing Date	Number	
3.1	Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2	Certificate of Amendment to Restated Certificate of Incorporation filed on May 10, 2013	8-K	5/14/2013	3.1	
3.3	Amended and Restated Bylaws	8-K	11/18/2011	3.2	
4.1	Form of the Registrant's Common Stock Certificate	S-1/A	10/26/2011	4.1	
4.2	Reference is made to Exhibits 3.1, 3.2 and 3.3 hereof				
10.1	License Agreement dated September 13, 2005 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.46	X
10.1.1	Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.47	X
10.1.2	Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.48	X
10.1.3	Amendment to License Agreement dated February 13, 2007 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.49	X
10.1.4	Amendment dated March 28, 2006 to the License Agreement by and between the Company and Georgia Regents Research Institute, Inc., formerly known as Medical College of Georgia Research Institute	10-Q	11/10/2014	10.3	X
10.1.5	Amendment to License Agreement dated July 10, 2014 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.4	X
31.1	Certification of principal executive officer required by Rule 13a-14(a) / 15d-14(a)				X
31.2	Certification of principal financial officer required by Rule 13a-14(a) / 15d-14(a)				X
32.1#	Section 1350 Certification				X
101.INS‡	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				X
101.SCH‡	XBRL Taxonomy Extension Schema Document				X
101.CAL‡	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF‡	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB‡	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE‡	XBRL Taxonomy Extension Presentation Linkbase Document				X

"The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NewLink Genetics Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing."

‡ Filed herewith electronically.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

NEWLINK GENETICS CORPORATION

By: /s/ Charles J. Link, Jr.
Charles J. Link, Jr.
Chief Executive Officer
(Principal Executive Officer)
Date: May 8, 2019

By: /s/ Carl W. Langren
Carl W. Langren
Chief Financial Officer and Secretary
(Principal Financial Officer)
Date: May 8, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the quarterly period ended June 30, 2019.

o **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the transition period from to .
Commission File Number
001-35342

NEWLINK GENETICS CORPORATION
(Exact name of Registrant as specified in Its Charter)

Delaware	**42-1491350**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2503 South Loop Drive
Ames, Iowa 50010
(515) 296-5555
(Address, including zip code, and telephone number, including area code, of principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	NLNK	The Nasdaq Stock Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer ☒	Smaller reporting company ☒
Emerging growth company o	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☒

As of August 6, 2019, there were 37,312,620 shares of the registrant’s Common Stock, par value $0.01 per share, outstanding.

NewLink Genetics Corporation

FORM 10-Q

Table of Contents

PART I

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share data)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 105,372	$ 120,738
Prepaid expenses and other current assets	4,015	5,536
Income tax receivable	353	339
Other receivables	458	459
Total current assets	110,198	127,072
Property and equipment, net	3,314	

3,727

Right-of-use asset

7,159

—

Income tax receivable

140

140

Total non-current assets

10,613

3,867

Total assets
$
120,811

$
130,939

Liabilities and Stockholders’ Equity

Current liabilities:

Accounts payable
$
689

$
555

Accrued expenses

7,235

8,139

Current portion of deferred rent

—

Current portion of lease liability

641

—

Current portion of notes payable

63

61

Total current liabilities

8,628

8,847

Long-term liabilities:

Royalty obligation payable to Iowa Economic Development Authority

6,000

6,000

Notes payable

11

43

Lease liability

7,485

—

Deferred rent

—

906

Total long-term liabilities

13,496

6,949

Total liabilities

22,124

15,796			
Stockholders’ equity:			
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at June 30, 2019 and December 31, 2018; issued and outstanding shares — 0 at June 30, 2019 and December 31, 2018	—		—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at June 30, 2019 and December 31, 2018; issued 37,413,093 and 37,343,547 at June 30, 2019 and December 31, 2018, respectively; and outstanding 37,300,960 and 37,251,220 at June 30, 2019 and December 31, 2018, respectively	373		373
Additional paid-in capital	410,946		407,199
Treasury stock, at cost: 112,133 and 92,327 shares at June 30, 2019 and December 31, 2018, respectively	(1,450)		(1,417)
Accumulated deficit	(311,182)		(291,012)
Total stockholders’ equity	98,687		115,143
Total liabilities and stockholders’ equity	$ 120,811		$ 130,939

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
Condensed Consolidated Statements
of Operations
(unaudited)
(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Operating revenues:				
Grant revenue	$ —	$ 1,884	$ —	$ 11,268
Licensing and collaboration revenue	151	368	257	884
Total operating revenues	151	2,252	257	12,152

Operating expenses:				
Research and development	5,237	12,088	10,440	32,402
General and administrative	5,638	7,912	11,205	16,204
Total operating expenses	10,875	20,000	21,645	48,606
Loss from operations	(10,724)	(17,748)	(21,388)	(36,454)

Other income and expense:

Miscellaneous (expense) income, net

(10
)

10

(5
)

34

Interest income

624

461

1,248

846

Interest expense

(24
)

(36
)

(25
)

(49
)

Other income, net

590

435

1,218

831

Net loss before taxes

(10,134)	(17,313)	(20,170)	(35,623)	
Income tax benefit	—	—	—	—
Net loss	$ (10,134)	$ (17,313)	$ (20,170)	$ (35,623)
Basic and diluted loss per share	$ (0.27)	$ (0.47)	$ (0.54)	$

(0.96
)

Basic and diluted average shares outstanding

37,276,443

37,165,529

37,275,954

37,160,334

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
Condensed Consolidated Statement of Stockholders' Equity
(unaudited)
(In thousands, except share data)

Six Month Period ended June 30, 2019

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2018	37,251,220	$ 373	$ 407,199	$ (1,417)	$ (291,012)	$ 115,143
Share-based compensation	—	—	1,944	—	—	1,944
Restricted stock vested	44,329					

—

—

—

—

—

Repurchase of common stock

(19,447
)

—

—

(32
)

—

(32
)

Net loss

—

—

—

—

(10,036
)

(10,036
)

Balance at March 31, 2019

37,276,102

373

409,143

(1,449
)

(301,048
)

107,019

Share-based compensation

—

—

1,773

—

—

1,773

Restricted stock vested

1,250

—

—

—

—

—

Sales of shares under stock purchase plan

23,967

—

30

—

—

30

Repurchase of common stock

(359
)

—

—

(1
)

—

(1
)
Net loss

—

—

—

—

(10,134
)

(10,134
)
Balance at June 30, 2019

37,300,960

$
373

$
410,946

$
(1,450
)
$
(311,182
)
$
98,687

	Six Month Period ended June 30, 2018					
	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2017	37,109,556	$ 372	$ 389,786	$ (1,142)	$ (237,459)	$ 151,557
Share-based compensation	—	—	4,820	—	—	4,820
Restricted stock vested	84,262	1	105	—	—	106
Sales of shares under stock purchase plan	—	—	—	—	—	—
Repurchase of common stock	(28,720)	—	—	(261)	—	(261)
Cumulative effect of accounting change	—	—	—	—	42	42
Net loss	—	—	—	—	(18,310)	(18,310)

Balance at March 31, 2018	37,165,098	373	394,711	(1,403)	(255,727)	137,954
Share-based compensation	—	—	4,177	—	—	4,177
Restricted stock vested	1,250	—	—	—	—	—
Sales of shares under stock purchase plan	32,111	—	130	—	—	130
Repurchase of common stock	(359)	—	—	(2)	—	(2)
Net loss	—	—	—	—	(17,313)	(17,313)
Balance at June 30, 2018	37,198,100	$ 373	$ 399,018	$ (1,405)	$ (273,040)	$ 124,946

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Six Months Ended June 30,	
	2019	**2018**
Cash Flows From Operating Activities		
Net loss	$ (20,170)	$ (35,623)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	3,717	8,997
Depreciation and amortization	399	637
Gain on sale of fixed assets	5	(34)
Amortization of right-of-use asset and change in operating lease liability	(32)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets		

1,521

519

Other receivables

1

9,865

Accounts payable and accrued expenses

(770
)

(5,862
)
Income taxes receivable

(14
)

(4
)
Unearned revenue

—

(56
)
Deferred rent

—

(51
)
Net cash used in operating activities

(15,343
)

(21,612
)
Cash Flows From Investing Activities

Purchase of equipment

—

(7
)
Proceeds on sale of equipment

9

108	
Net cash provided by investing activities	
9	
101	
Cash Flows From Financing Activities	
Issuance of common stock, net of offering costs	
30	
236	
Repurchase of common stock	
(33)	
(263)	
Principal payments on notes payable	
(29)	
(104)	
Net cash used in financing activities	
(32)	
(131)	
Net decrease in cash and cash equivalents	
(15,366)	
(21,642)	
Cash and cash equivalents at beginning of period	
120,738	
158,708	
Cash and cash equivalents at end of period	
$	
105,372	
$	
137,066	

Supplemental disclosure of cash flows information:

Cash paid for interest	$	2	
	$	5	
Cash paid for taxes, net	$	14	
	$	5	

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Description of Business

On June 4, 1999, NewLink Genetics Corporation (NewLink) was incorporated as a Delaware corporation. NewLink was formed to develop treatments for patients with cancer and other diseases. NewLink initiated operations in April 2000.

NewLink and its subsidiaries (the Company) are devoting substantially all of their efforts toward research and development. The Company has never earned revenue from commercial sales of its drugs.

The accompanying condensed consolidated financial statements as of June 30, 2019 and for the three and six months ended June 30, 2019 have been prepared assuming the Company will continue as a going concern. The Company raised net proceeds of $37.6 million from its initial public offering in 2011, completed a follow-on offering of its common stock raising net proceeds of $49.0 million in 2013, and raised an additional $58.7 million in net proceeds from an at the market (ATM) offering completed in 2015.

During 2017, the Company sold 1,940,656 shares of its common stock under an ATM offering, with aggregate net proceeds of $19.3 million after commissions of $398,000 paid to Cantor Fitzgerald & Co. (Cantor) as the placement agent, and other costs of $163,000. In October 2017, the Company sold 5,750,000 of its shares of common stock in a public offering for aggregate net proceeds of $55.2 million after underwriters' discounts, commissions and other expenses of $3.7 million.

The Company's cash and cash equivalents as of June 30, 2019 are expected to be adequate to satisfy the Company's liquidity requirements through 2021. If available liquidity becomes insufficient to meet the Company's operating obligations as they come due, the Company's plans include selling additional shares of common stock, alternative funding arrangements and/or reducing expenditures as necessary to meet the Company's cash requirements. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity. Failure by the Company to successfully execute its plans or otherwise address its liquidity needs may have a material adverse effect on its business and financial position, and may materially affect the Company's ability to continue as a going concern.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared and presented by the Company in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and the rules and regulations of the U.S. Securities and Exchange Commission (the SEC), and, in management's opinion, reflect all adjustments necessary to present fairly the Company's interim condensed financial information.

Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2018, included in the Company's Annual Report on Form 10-K. The financial results for any interim period are not necessarily indicative of financial results for the full year.

3. Significant Accounting Policies

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The condensed consolidated financial statements include the financial statements of NewLink and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Financial Instruments and Concentrations of Credit Risk

Cash and cash equivalents, receivables, and accounts payable are recorded at cost, which approximates fair value based on the short-term nature of these financial instruments. The carrying value of notes payable was $74,000 and $104,000 as of June 30, 2019 and December 31, 2018, respectively, which approximate fair value using Level 2 inputs (computed in accordance with ASC 820). The Company is unable to estimate the fair value of the royalty obligation based on future product sales, as the timing of payments, if any, is uncertain.

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, the Company's cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, the Company invests its excess cash primarily in high-quality securities such as certificates of deposit and money market funds.

Property and Equipment

Property and equipment are capitalized as the Company believes they have alternative future uses and are stated at cost, less accumulated depreciation of $7.3 million and $7.0 million as of June 30, 2019 and December 31, 2018, respectively. Depreciation on all property and equipment is calculated on the straight-line method over the shorter of the lease term or estimated useful life of the asset. Computer equipment has useful lives of three to five years, lab equipment has a useful life of five years, and contract manufacturing organization equipment has a useful life of five years.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02 (Topic 842), Leases, to improve financial reporting for leasing transactions. The Company adopted the standard on January 1, 2019 using the modified retrospective method, as required, applying the new standard to all leases existing as of the date of initial application. The Company has elected that the date of the initial application, January 1, 2019, will be the effective date. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. The Company elected the "package of practical expedients", which permits the Company not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect to apply the use-of-hindsight or the practical expedient pertaining to land easements; as the latter is not applicable to the Company.

Upon adoption of the standard, the Company recorded a lease liability of $8.5 million and a right of use asset of $7.5 million associated with these leases. Included in the right-of-use asset are lease incentives that were previously recorded as deferred rent liability of $1.0 million as of December 31, 2018 on the consolidated balance sheet. There was no material impact to the consolidated statement of operations.

4. Revenues

Revenue Recognition

Revenues are recognized under Topic 606 when control of the promised goods or services is transferred to the Company's customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Prior to transferring the government contracts over to Merck Sharp & Dohme Corp. (Merck) in June 2018, the Company received payments from government entities under its grants and contracts with the Department of Defense and the United States Department of Health and Human Services (HHS). These agreements provided the Company cost reimbursement plus a percentage for certain types of expenditures in return for research and development activities over a contractually defined period. Grant revenues were recognized over time and measured using the input method. The Company used labor costs and subcontractor fees as inputs to measure progress towards satisfying its performance obligations under these agreements. Under this method, the Company recognized revenue generally in the period during which the related costs were incurred, in an amount that reflected the consideration the Company expected to be entitled to in exchange for those goods or services transferred to the government entities due to the government entities' control over the research and development activities.

The grants and contracts with government entities were fully transferred to Merck as of June 2018. Accordingly, during the six months ended June 30, 2019, the Company recognized no grant revenue. The Company had $273,000 and $309,000 of receivables relating to the government contracts on the balance sheet as of June 30, 2019 and December 31, 2018, respectively. The Company had $40,000 and $54,000 of accrued expenses for subcontractor fees incurred under the government contracts as of June 30, 2019 and December 31, 2018, respectively.

5. License and Research Collaboration Agreement

Merck Sharp & Dohme Corp.

In November 2014, the Company entered into a licensing and collaboration agreement (the Merck Agreement) with Merck to develop, manufacture and commercialize rVSV-ZEBOV-GP, an Ebola vaccine the Company licensed from the Public Health Agency of Canada (PHAC). Under the terms of the Merck Agreement, the Company granted Merck an exclusive, royalty bearing license to rVSV-ZEBOV-GP and related technology. Under the Merck Agreement, the Company received a $30.0 million non-refundable, upfront payment in December 2014, and a one-time $20.0 million non-refundable milestone payment in February 2015 upon the initiation of the pivotal clinical trial using the current rVSV-ZEBOV-GP vaccine product as one arm of the trial. In addition, the Company can receive escalating royalties on potential commercial sales by Merck of the current product candidate ranging from single digit to double digits on the rVSV-ZEBOV-GP license agreement product sales and escalating royalties on potential commercial sales by Merck of products other than current products within the Company's patent rights ranging from low to high single digit, on increasing levels of annual net sales worldwide. Merck is expected to lead the development of rVSV-ZEBOV-GP and any other rVSV-based viral hemorrhagic fever vaccine product candidates in order to create a marketable product safe for human use.

The Merck Agreement was amended on December 5, 2017 in connection with our entry into an amended and restated PHAC license on December 5, 2017. The amended Merck Agreement absolves our subsidiary, BioProtection Systems Corporation (BPS), from any future obligation to negotiate or amend the terms of the PHAC license, converts the scope of Merck's sublicense under PHAC's intellectual property rights to be non-exclusive in the Ebola Sudan field of use, and requires Merck to reimburse us in certain circumstances where we may be obligated to pay royalties to PHAC as a result of Merck's product sales but Merck would not otherwise be obligated to pay a royalty to us. On April 26, 2018, the Company entered into an agreement with Merck, the U.S. BioMedical Advanced Research and Development Authority (BARDA), and the Defense Threat Reduction Agency (DTRA) to transfer the government grants from BARDA and DTRA to Merck. The transfer was completed in June 2018 and Merck has replaced the Company as the prime contractor on all such grants.

For the three and six months ended June 30, 2019, the Company recognized revenues under the amended Merck Agreement of $151,000 and $257,000, respectively, for work the Company performed as a subcontractor of Merck under the government contracts that were transferred to Merck. For the three and six months ended June 30, 2018, the Company recognized license and collaboration revenue under the amended Merck Agreement of $368,000 and $828,000, respectively, for the reimbursement of costs not covered under government contracts.

6. Common Stock Equity Incentive Plan

2009 Equity Incentive Plan

In April 2000, the stockholders approved the Company's 2000 Equity Incentive Plan (the 2000 Plan), in July 2009, the stockholders approved the Company's 2009 Equity Incentive Plan (the 2009 Plan), and in May 2019, the stockholders approved to amend and extend the Company's 2009 Equity Incentive Plan (the 2019 Plan). Following the approval of the 2019 Plan, no additional stock awards will be granted under the 2009 Plan. Shares that remained available for issuance pursuant to the exercise of options or issuance or settlement of stock awards under the 2009 Plan became available for issuance pursuant to the 2019 Plan and all shares that would have otherwise returned to the 2009 Plan became available for issuance pursuant to the 2019 Plan. Under the provisions of the 2019 Plan, the Company may grant the following types of common stock awards:

- Incentive Stock Options
- Nonstatutory Stock Options

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- Restricted Stock Awards
- Stock Appreciation Rights

Awards under the 2019 Plan, as amended, may be made to officers, employees, members of the Board of Directors, advisors, and consultants to the Company. As of June 30, 2019, there were 12,400,653 shares of common stock authorized for the 2019 Plan and 2,747,181 shares remained available for issuance.

The following table summarizes the authorized increases of common stock under the 2009 Plan:

Date Authorized	Authorized Shares Added
May 15, 2010	1,238,095
January 7, 2011	714,285
January 1, 2012	823,649
January 1, 2013	839,407
January 1, 2014	1,062,920
January 1, 2015	1,119,233
January 1, 2016	1,152,565
January 1, 2017	1,166,546
January 1, 2018	1,484,382
January 1, 2019	1,490,048

The increases in the authorized shares of common stock under the 2009 Plan in 2010 and 2011 were approved by the Company's stockholders. The increases in the authorized shares of common stock under the 2009 Plan in 2012 through 2019 were made pursuant to an "evergreen provision," in accordance with which, on January 1 of each year, from 2013 to (and including) 2019, a number of shares of common stock in an amount equal to 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or such lesser amount of shares (or no shares) approved by the Company's Board of Directors, was added or will be added to the shares reserved under the 2009 Plan.

On May 9, 2019, the Company's stockholders approved an amendment to the 2009 Plan which, among other modifications, included decreasing the automatic annual "evergreen provision" from 4% to 3%, in accordance with which, on January 1 of each year, from 2020 to (and including) 2029, a number of shares of common stock in an amount equal to 3% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or such lesser amount of shares (or no shares) approved by the Company's Board of Directors, was added or will be added to the shares reserved under the 2009 Plan.

2010 Non-Employee Directors' Stock Award Plan

Under the terms of the Company's 2010 Non-Employee Directors' Stock Award Plan (the Directors' Plan) which became effective on November 10, 2011, 238,095 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 161,905 shares of common stock were added to the shares reserved for future issuance under the Directors' Plan. As of June 30, 2019, no shares remain available for issuance under the Directors' Plan.

2010 Employee Stock Purchase Plan

Under the terms of the Company's 2010 Employee Stock Purchase Plan (the 2010 Purchase Plan), which became effective on November 10, 2011, 214,285 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 185,715 shares of common stock were added to the shares reserved for future issuance under the 2010 Purchase Plan. As of June 30, 2019, 29,542 shares remained available for issuance under the 2010 Purchase Plan.

Share-based Compensation

Share-based compensation expense for the three months ended June 30, 2019 and 2018 was $1.8 million and $4.2 million, respectively. Share-based compensation expense for the six months ended June 30, 2019 and 2018 was

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$3.7 million and $9.0 million, respectively. Share-based compensation expense is allocated between research and development and general and administrative expenses within the condensed consolidated statements of operations.

As of June 30, 2019, the total compensation cost related to nonvested option awards not yet recognized was $7.0 million and the weighted-average period over which it is expected to be recognized is 2.5 years.

Stock Options and Performance Stock Options

The following table summarizes the stock option activity, including options with market and performance conditions, for the six months ended June 30, 2019:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	7,979,644	$ 11.86	4.5
Options granted	1,561,675	1.80	
Options exercised	—	—	
Options forfeited	(29,697)	8.02	
Options expired	(1,001,911)		

3.92

Outstanding at end of period

8,509,711

$
10.96

5.5

Options exercisable at end of period

5,847,372

$
13.78

3.9

The Company estimates the fair value of each stock option grant on the date of grant using a Black-Scholes option pricing model. For stock option grants issued with a market condition, the Company used a Monte Carlo simulation valuation model to determine the grant date fair value.

The following table summarizes the range of assumptions used to estimate the fair value of stock options granted, including those options granted with a market condition, during the six months ended June 30, 2019:

Risk-free interest rate	2.3% to 2.7%
Expected dividend yield	—%
Expected volatility	77.6% to 79.6%
Expected term (in years)	4.0 to 7.7
Weighted-average grant-date fair value per share	$1.28

No options were exercised during the six months ended June 30, 2019. The fair value of awards vested during the six months ended June 30, 2019 was $4.0 million.

During the six months ended June 30, 2019, the Company’s Board of Directors approved and granted 650,000 shares of equity awards to certain executives with either market or performance conditions. The equity awards had a weighted-average grant date fair value per share of $1.24. The equity awards vest upon the achievement of certain performance conditions. Certain performance conditions relating to the equity awards granted in 2017 were met during the three and six months ended June 30, 2019 and 79,849 shares vested.

Restricted Stock and Performance Restricted Stock

Restricted stock is common stock that is subject to restrictions, including risks of forfeiture, determined by the planning committee of the Board of Directors in its sole discretion, for as long as such common stock remains subject to any such restrictions. A holder of restricted stock has all rights of a stockholder with respect to such stock, including the right to vote and to receive dividends thereon, except as otherwise provided in the award agreement relating to such award. Restricted stock awards are classified as equity within the consolidated balance sheets. The fair value of each restricted stock grant is estimated on the date of grant using the closing price of the Company's common stock on The Nasdaq Stock Market on the date of grant.

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A summary of the Company's unvested restricted stock, including restricted stock with performance conditions, at June 30, 2019 and changes during the six months ended June 30, 2019 are as follows:

	Number of restricted stock shares	Weighted average grant date fair value
Unvested at beginning of period	68,585	$ 37.75
Granted	—	—
Vested	(45,579)	39.23
Forfeited/cancelled	—	—
Unvested at end of period	23,006	$ 34.82

As of June 30, 2019, the total remaining unrecognized compensation cost related to restricted stock was approximately $476,000 and is expected to be recognized over a weighted-average period of 0.5 years.

The Company does not have a formal policy regarding the source of shares issued upon exercise of stock options or issuance of restricted stock. The Company expects shares issued to be issued from treasury shares or new shares.

Option Exchange Program

On June 20, 2019, the Company filed a Tender Offer Statement on Schedule TO relating to an option exchange program for its officers and employees (Option Exchange) to exchange certain stock options to purchase up to an aggregate of 5,849,059 shares of the Company's common stock that had been granted to eligible holders, for a lesser number of new stock options with a lower exercise price. Stock options granted prior to December 31, 2018 with an exercise price equal to or greater than $2.97 and held by eligible holders in continuous service through the termination of the Option Exchange were eligible for exchange in the program.

The eligible shares were exercisable for a reduced number of shares based on the following exchange ratios:

Exercise Price Range per Share	Number of Outstanding Eligible Options	Exchange Ratio (Surrendered Stock Options to New Stock Options)
$2.97-$10.99	2,725,812	2 to 1
$11.00-$24.99	720,373	3 to 1
$25.00-And Up	468,671	4 to 1

Upon the expiration time of the Option Exchange on July 31, 2019, 45 eligible employees and 5 eligible directors had tendered an aggregate of 3,914,856 options, representing 67% of the total eligible options, for 1,720,341 new options to purchase shares of common stock. Each new stock option was

granted on July 31, 2019, pursuant to the Company's 2009 Plan, as amended, with an exercise price per share of $1.77 per share, which was the closing market price on the grant date of the new options.

7. Leases

The Company has certain facility leases with non-cancellable terms ranging between one and three years, with certain renewal options.

The Company records lease liabilities based on the present value of lease payments over the lease term using an incremental borrowing rate to discount its lease liabilities, as the rate implicit in the lease is typically not readily determinable. To compute the present value of the lease liability, the Company used a weighted-average discount rate of 5%. Certain lease agreements include renewal options that are under the Company's control. The Company includes optional renewal periods in the lease term only when it is reasonably certain that the Company will exercise its option. The weighted-average remaining lease term as of June 30, 2019 is 11.5 years.

The Company does not separate lease components from non-lease components. Variable lease payments include payments to lessors for taxes, maintenance, insurance and other operating costs as well as payments that are adjusted based on an index or rate. The Company's lease agreements do not contain any residual value guarantees or restrictive covenants.

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Future minimum lease payments under the non-cancellable operating leases (with initial or remaining lease terms in excess of one year) as of June 30, 2019 are as follows (in thousands):

For the Year Ended December 31:	
2019	$ 542
2020	1,004
2021	923
2022	906
2023	909
Thereafter	6,570
Total future minimum lease payments	10,854
Less: imputed interest	(2,728)
Total	$ 8,126

The following table summarizes the aggregate undiscounted non-cancelable future minimum lease payments for operating leases under the prior lease standard as of December 31, 2018 (in thousands):

For the Year Ended December 31:	
2019	$ 1,105
2020	1,004
2021	923
2022	906
2023	909
Thereafter	6,570
Total	$ 11,417

8. Income Taxes

For the three and six months ended June 30, 2019 and 2018, the Company has recorded no income tax benefit (expense). The income tax amount for the three and six months ended June 30, 2019 and 2018 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to a full valuation allowance recorded against anticipated net operating loss carryforwards.

The Company has a noncurrent income tax receivable as of June 30, 2019 for $140,000 which was recorded as an income tax benefit in 2017 and is for the receipt of alternative minimum tax (AMT) credit carryovers. The Tax Cuts and Jobs Act of 2017 (the Tax Act), provides that the AMT credit carryovers are partially refundable beginning in 2018 as an offset to a tax liability. The Company expects the amount to be fully refunded by 2021.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and

tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of June 30, 2019 and December 31, 2018, respectively, due to the uncertainty of future recoverability.

The Company has a reserve for uncertain tax positions related to state tax matters of $653,000 as of June 30, 2019 recorded within Accrued Expenses in the condensed consolidated balance sheet, which includes the accrual of interest and penalties. The Company does not expect the amount to change significantly within the next 12 months.

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9. Net Loss per Share of Common Stock

Basic loss per share is based upon the weighted-average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. Diluted loss per share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average potentially dilutive common stock equivalents during the period when the effect is dilutive.

The following table presents the computation of basic and diluted loss per share of common stock (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Loss attributable to common stockholders	$ (10,134)	$ (17,313)	$ (20,170)	$ (35,623)
Basic and diluted weighted-average shares outstanding	37,276,443	37,165,529	37,275,954	37,160,334
Basic and diluted loss per share	$ (0.27)	$ (0.47)	$ (0.54)	$ (0.96)

All common stock equivalents are excluded from the computation of diluted loss per share during periods in which losses are reported since the result would be anti-dilutive. As of June 30, 2019, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 8,509,711 and 23,006, respectively. As of June 30, 2018, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 8,542,990 and 94,344, respectively.

10. Restructuring Charges

The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. Employee severance costs are accrued when the restructuring actions are probable and estimable. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits, is recognized ratably over the future service period. The Company also records costs incurred with contract terminations associated with restructuring activities.

In July 2018, the Company completed an organizational review of its clinical programs and reduced its headcount by approximately 30% as compared to June 30, 2018 and made several changes to senior leadership effective July 26, 2018 in order to conserve resources to advance its clinical development programs. No restructuring charges were recorded during the three and six months ended June 30, 2019 and 2018.

The following table shows the amount accrued for restructuring activities which is recorded within Accrued Expenses in the condensed consolidated balance sheet (in thousands):

	Employee Severance Cost	Total
Balance as of December 31, 2018	$ 649	$ 649
Expensed	—	—
Cash Payments	466	466
Balance as of June 30, 2019	$ 183	$ 183

11. Commitments and Contingencies

From time to time, claims are asserted against the Company arising in the ordinary course of business. In the opinion of management, liabilities, if any, arising from existing claims are not expected to have a material effect on the Company’s earnings, financial position, or liquidity.

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York (the Court), captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545 (the Securities Action). Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action.

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On October 31, 2016, the lead plaintiffs filed an amended complaint asserting claims under the federal securities laws against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian, (collectively, the Defendants). The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. On March 29, 2018, the Court dismissed the amended complaint for failure to state a claim, without prejudice, and gave the lead plaintiffs until May 4, 2018 to file any amended complaint attempting to remedy the defects in their claims. On May 4, 2018, the lead plaintiffs filed a second amended complaint asserting claims under the federal securities laws against the Defendants. Like the first amended complaint, the second amended complaint alleges that the Defendants made material false and/or misleading statements or omissions relating to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L that caused losses to the Company's investors. The lead plaintiffs do not quantify any alleged damages in the second amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the second amended complaint on July 31, 2018. On February 13, 2019, the Court dismissed the second amended complaint for failure to state a claim, with prejudice, and closed the case. On March 14, 2019, lead plaintiffs filed a notice of appeal. The briefing on lead plaintiffs' appeal was completed in early July 2019 and oral argument before the Second Circuit Court of Appeals is currently scheduled for the week of October 21, 2019. The Company intends to continue defending the Securities Action vigorously.

On or about April 26, 2017, Ronald Morrow filed a shareholder derivative lawsuit on behalf of the Company in the United States District Court for the Southern District of New York, or the Court, against the Company's Chief Executive Officer Charles J. Link, Jr., the Company's Chief Medical Officer and President Nicholas Vahanian, and Company directors Thomas A. Raffin, Joseph Saluri, Ernest J. Talarico, III, Paul R. Edick, Paolo Pucci, and Lota S. Zoth (collectively, the Morrow Defendants), captioned Morrow v. Link., et al., Case 1:17-cv-03039 (the Morrow Action). The complaint alleges that the Morrow Defendants caused the Company to issue false statements in its 2016 proxy statement regarding risk management and compensation matters in violation of federal securities law. The complaint also asserts state law claims against the Morrow Defendants for breaches of fiduciary duties, unjust enrichment, abuse of control, insider trading, gross mismanagement, and corporate waste, alleging that the Morrow Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L, awarded themselves excessive compensation, engaged in illegal insider trading, and grossly mismanaged the Company. The plaintiff does not quantify any alleged damages in the complaint but seeks restitution for damages to the Company, attorneys' fees, costs, and expenses, as well as an order directing that proposals for strengthening board oversight be put to a vote of the Company's shareholders. The language for such proposals is not specified in the complaint. The plaintiff also contemporaneously filed a statement of relatedness, informing the Court that the Morrow Action is related to Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545. On May 19, 2017, the plaintiff dismissed the Morrow Action without prejudice. Also on May 19, 2017, plaintiffs' counsel in the Morrow Action filed a new shareholder derivative complaint that is substantively identical to the Morrow Action, except that the plaintiff is Rickey Ely. The latter action is captioned Ely v. Link, et al., Case 17-cv-3799, or the Ely Action. By agreement of the parties and order dated June 26, 2017, the Court temporarily stayed the Ely Action until the Securities Action is dismissed or otherwise finally resolved. Under the terms of the stay, the plaintiff in the Ely Action has until March 15, 2019 (30 days after dismissal of the Securities Action with prejudice) to file an amended derivative complaint or rest upon the current derivative complaint. By further agreement of the parties, dated March 15, 2019, the Ely Action will continue to be stayed pending the outcome of the appeal in the Securities Action. If the Securities Action continues to be dismissed in its entirety following its appeal plaintiff in the Ely Action has agreed to withdraw or dismiss the action, with prejudice. The Company disputes the claims in the Ely Action and intends to defend against them vigorously.

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12. Subsequent Events

Charles J. Link, Jr, M.D. retired from the Company and the Board of Directors, effective August 3, 2019. Dr. Link entered into a separation agreement with the Company under which he will be provided with certain compensation and benefits, as described in the Form 8-K filed with the U.S. Securities and Exchange Commission on August 2, 2019. In connection with Dr. Link's retirement, the Company expects to report a severance charge in the third quarter ending September 30, 2019.

In conjunction with the retirement of Dr. Link, the Board formed the Office of the Chief Executive Officer with the purpose to allow for effective management of the Company's business during the transition in leadership and the further advancement of the Company's strategic goals. Effective August 3, 2019, the members of the Office of the Chief Executive Officer are: Carl Langren, Chief Financial Officer; Eugene Kennedy, M.D., Chief Medical Officer; Brad Powers, General Counsel; and Lori Lawley, Vice President, Finance and Controller. Reporting to the Board of Directors, the members of the Office of the Chief Executive Officer have been given full executive authority and will oversee the execution of the Company's operations and strategic initiatives.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and such statements are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information available to our management as of the date hereof. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: our ongoing and planned preclinical studies and clinical trials; the timing of the release of the results of data from ongoing preclinical studies and clinical trials; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the clinical utility of our product candidates; our plans to leverage our existing technologies to discover and develop additional product candidates; our ability to quickly and efficiently identify and develop product candidates; our intellectual property position; the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; plans to develop, commercialize, market and manufacture our product candidates; and other risks and uncertainties, including those described in Part II, Item 1A, "Risk Factors" of this Quarterly Report and in our other periodic reports filed from time to time with the Securities and Exchange Commission, or SEC, including our Annual Report on Form 10-K for the year ended December 31, 2018. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including those risks. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Overview

NewLink Genetics Corporation (the Company, NewLink, we, our or us) is a clinical-stage immuno-oncology company focused on developing novel immunotherapeutic products for the treatment of patients with cancer. Our leading small-molecule product candidates currently in clinical development target the indoleamine-2, 3-dioxygenase (IDO) pathway, which is one of the key pathways for cancer immune escape. These product candidates, indoximod and NLG802 (a prodrug of indoximod), are IDO pathway inhibitors with mechanisms of action that center around breaking the immune system's tolerance to cancer. We also have an additional small molecule product candidate, NLG207 (formerly CRLX101), which is a nanoparticle-drug conjugate (NDC) consisting of a cyclodextrin-based polymer backbone linked to camptothecin, a topoisomerase 1 inhibitor.

Based on early clinical data from our Phase 1/2 clinical trials, our clinical program is focused on targeted indications with great unmet need where indoximod, NLG802, and NLG207 have produced encouraging early data. We plan to advance our core clinical programs and expect to present additional data supporting these research efforts in 2019. We anticipate presenting updated Phase 1b data for indoximod for the cohort of pediatric patients with newly diagnosed treatment-naïve diffuse intrinsic pontine glioma (DIPG).

IDO Pathway Inhibitors

In cancer, the IDO pathway regulates immune response by suppressing T-cell activation, which enables cancer to avoid immune response. IDO is overexpressed in many cancers, both within tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor-draining lymph nodes, thereby promoting peripheral tolerance to tumor associated antigens (TAAs). When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system.

The IDO pathway refers to a series of reactions initiated by IDO that result in the reduction of the amino acid tryptophan in the local tumor environment. We believe the local presence of tryptophan in adequate concentrations

promotes antitumor T-cells, and the local reduction of tryptophan combined with the presence of the breakdown product of tryptophan metabolism, kynurenine, is understood to suppress the activation of T-cells. Preclinical and, increasingly, clinical data suggest that IDO pathway inhibitors may also enhance the anti-tumor effects of other immunotherapies, chemotherapies and radiation when used as a combination therapy for patients with cancer.

We have a clinical development program primarily focused on the IDO pathway. Our small-molecule IDO pathway inhibitor product candidates currently in clinical development include indoximod and NLG802. Our product candidates are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. Indoximod acts as a tryptophan mimetic, thereby signaling the activation of antitumor T-cells by the activation of mammalian target of rapamycin (mTOR), acts directly on T-cells, and modulates aryl hydrocarbon receptor (AhR)-mediated effects.

We have observed an encouraging safety profile for our IDO pathway inhibitors. They are also orally bioavailable and we believe they offer the potential to be synergistic with other therapies such as radiation, chemotherapy, vaccination and immunotherapies involving other checkpoint inhibitors such as anti-PD-1, anti-programmed cell death ligand-1 (PD-L1), or anti-cytotoxic T-lymphocyte antigen 4 (CLTA4). Clinical data suggest an increase in clinical activity without adding significant toxicity.

Indoximod

Indoximod, our lead IDO pathway inhibitor, is currently in clinical development in combination with other cancer therapeutics for patients with DIPG, acute myeloid leukemia, and melanoma. We believe there may be additional opportunities to apply indoximod to a broader set of cancer indications. More than 900 patients have been treated with indoximod to date and it has generally been well-tolerated, including in combination with PD-1 checkpoint inhibitors, various chemotherapy agents, radiation, and a cancer vaccine.

A tablet formulation of indoximod hydrochloride has been developed for adult patients and a sprinkle formulation is being developed for pediatric indications. We plan to use our new tablet formulation of indoximod in future clinical trials.

Two U.S. patents covering both the salt and prodrug formulations of indoximod were issued in the U.S. on August 15, 2017 and February 19, 2019 providing exclusivity until at least 2036. We are currently pursuing international patent coverage for these formulations.

NLG802

NLG802 is a prodrug of indoximod. NLG802 is intended to increase bioavailability and exposure to indoximod above levels currently achievable by direct oral administration of indoximod. We filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA), in the first quarter of 2017 and the first patient was dosed with NLG802 in a Phase 1 clinical trial in July 2017. The purpose of this Phase 1 trial is to assess preliminary safety and to determine the recommended dose for subsequent Phase 2 evaluations. NLG802 is a new chemical entity with patent coverage into 2036. We are also pursuing international patent coverage for NLG802.

In May 2019, we presented updated results for the Phase 1 dose escalation trial for NLG802 at the Immuno-Oncology 2019 World Congress. Pharmacokinetics (PK) results were also reported from this study. After continuous twice-daily dosing with NLG802 at all levels, significantly higher PK exposure was observed. At 1452 mg twice daily, the highest dose administered, NLG802 produced a 6-fold increase in Cmax and a 4.7-fold increase in AUC compared with molar equivalent indoximod dosing.

The treatment regimen was well tolerated with no NLG802-related serious adverse events reported. The recommended Phase 2 dose was established at 1452 mg BID based on achieving preclinical exposure levels required for pharmacodynamic effects of indoximod.

NLG919

NLG919, a direct enzymatic inhibitor, was previously in clinical development as part of our collaboration with Genentech, Inc. (Genentech). In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech (the Genentech Agreement). The Genentech Agreement provided for the development and commercialization of NLG919. On December 6, 2017, the Genentech Agreement with respect to NLG919 was terminated. As part of the partial termination, worldwide rights to NLG919 reverted to us and Genentech granted us

a license under certain of Genentech's intellectual property to develop and commercialize NLG919. We continue to explore the potential for further development and licensing opportunities but do not have an active program for the drug product candidate as of June 30, 2019.

Additional Product Candidates

NLG207

NLG207 is a NDC consisting of a cyclodextrin-based polymer backbone linked to camptothecin, a topoisomerase-1, or top-1, inhibitor. Because the vasculature in tumors is more permeable than normal tissue, we believe NDCs have the potential to enhance drug delivery to tumors by enabling gradual payload release inside cancer cells to augment antitumor activity while reducing off-target toxicity. NLG207 has been studied in more than 400 patients as monotherapy or in combination with other anticancer agents for patients with solid tumors.

A Phase 2 trial evaluating NLG207 plus paclitaxel for patients with recurrent ovarian, fallopian tube or primary peritoneal cancer was completed in collaboration with the Gynecological Oncology Group and the results of the trial were presented at the annual meeting for the American Association for Cancer Research on April 2, 2019.

Ebola Vaccine Candidate

In November 2014, we entered into the Merck Agreement to develop and potentially commercialize our rVSVΔG-ZEBOV-GP vaccine product candidate and other aspects of our vaccine technology. The rVSVΔG-ZEBOV-GP vaccine product candidate was originally developed by the Public Health Agency of Canada (PHAC) and is designed to utilize the rVSV vector to induce immunity against Ebola virus when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. Under the Merck Agreement, we received an upfront payment of $30.0 million in October 2014, and in February 2015 we received a milestone payment of $20.0 million. We have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved by the FDA and successfully commercialized by Merck. rVSVΔG-ZEBOV-GP is also eligible to receive a priority review voucher and we are entitled to a portion of the value of the voucher if it is granted. In addition to milestone payments from Merck, we were awarded contracts for development of the rVSVΔG-ZEBOV-GP from the U.S. BioMedical Advanced Research & Development Authority (BARDA), and the Defense Threat Reduction Agency (DTRA), totaling $52.1 million during 2016 and $67.0 million during 2014 and 2015. Funds of $2.1 million were de-obligated from the DTRA grant awards in 2017. We have received total awards of $118.8 million.

On April 26, 2018 we entered into an agreement with Merck, DTRA and BARDA to transfer the government grants from BARDA and DTRA to Merck. The transfer was completed in June 2018 and Merck has replaced us as the prime contractor on all such grants.

Restructuring Charges

In July 2018, the Company completed an organizational review of its clinical programs and reduced its headcount by approximately 30% as compared to June 30, 2018 and made several changes to senior leadership effective July 26, 2018 in order to conserve its resources. No restructuring charges were recorded during the three and six months ended June 30, 2019 relating to this reorganization.

Corporate Information

Founded in 1999, our executive offices and manufacturing facilities are located in the Iowa State University Research Park in Ames, Iowa. We have approximately 50,160 square feet, comprising executive office space and space dedicated to manufacturing, testing and product storage, leased with the Iowa State University Research Park Corporation. We have additional executive and administrative space in Austin, Texas and clinical, regulatory and executive offices in Wayne, Pennsylvania.

We incurred a net loss of $20.2 million for the six months ended June 30, 2019. We expect to continue to incur losses over the next several years as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

Critical Accounting Policies and Significant Judgments and Estimates

We have prepared our financial statements in accordance with U.S. GAAP which requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, expenses and related disclosures at the date of the financial statements, as well as revenues and expenses during the reporting periods. As such, to

understand our financial statements, it is important to understand our critical accounting policies. A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Actual results could, therefore, differ materially from these estimates under different assumptions or conditions.

Our Annual Report on Form 10-K for the year ended December 31, 2018 discusses our most critical accounting policies. Since December 31, 2018, there have been no material changes in the critical accounting policies discussed in our 2018 Annual Report.

Recent Accounting Pronouncements

We adopted ASC Topic 842 on January 1, 2019 and have disclosed the impact adoption had on our condensed consolidated financial statements within Note 3 of the "Notes to Condensed Consolidated Financial Statements" of this Form 10-Q. We do not believe that any other recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

Results of Operations

Comparison of the Three Months Ended June 30, 2019 and 2018

Revenues. Revenues for the three months ended June 30, 2019 were $151,000, a decrease of $2.1 million from $2.3 million for the same period in 2018. The decrease in revenue was due to a decrease in grant revenue of $1.9 million, primarily attributable to a decrease in billings under the government grant contracts which were fully transferred to Merck in June 2018, and a decrease of $217,000 in licensing revenue, attributable to lower billings to Merck. We recognized licensing revenue during the three months ended June 30, 2019 for work we performed as a subcontractor of Merck.

Research and Development Expenses. Research and development expenses for the three months ended June 30, 2019 were $5.2 million, a decrease of $6.9 million from $12.1 million for the same period in 2018. The decrease was primarily due to reductions of $2.4 million in contract research and manufacturing spend, $2.0 million in clinical trial expense, $1.8 million in personnel-related and stock compensation expense, $400,000 in supplies and licensing, and $300,000 in legal and consulting expense.

General and Administrative Expenses. General and administrative expenses for the three months ended June 30, 2019 were $5.6 million, a decrease of $2.3 million from $7.9 million for the same period in 2018. The decrease was due primarily to reductions of $1.9 million in personnel-related and stock compensation expense and $400,000 in supplies.

Income Tax Benefit. We did not record any income tax benefit for the three months ended June 30, 2019 and 2018, respectively.

Net Loss. The net loss for the three months ended June 30, 2019 was $10.1 million compared to a net loss of $17.3 million for the same period in 2018. The basic and diluted weighted-average shares of common stock outstanding for the three months ended June 30, 2019 were 37,276,443, resulting in a basic and diluted loss per share of $0.27. For the three months ended June 30, 2018, the basic and diluted weighted-average shares of common stock outstanding were 37,165,529, resulting in basic and diluted loss per share of $0.47.

Comparison of the Six Months Ended June 30, 2019 and 2018

Revenues. Revenues for the six months ended June 30, 2019 were $257,000, a decrease of $11.9 million from $12.2 million for the same period in 2018. The decrease in revenue was due to a decrease in grant revenue of $11.3 million, primarily attributable to a decrease in billings under the government grant contracts which were fully transferred to Merck in June 2018, and a decrease of $627,000 in licensing revenue, attributable to lower billings to Merck. We recognized licensing revenue during the six months ended June 30, 2019 for work we performed as a subcontractor of Merck.

Research and Development Expenses. Research and development expenses for the six months ended June 30, 2019 were $10.4 million, a decrease of $22.0 million from $32.4 million for the same period in 2018. The decrease was primarily due to reductions of $12.3 million in contract research and manufacturing spend, $4.1 million in personnel-related and stock compensation expense, $4.0 million in clinical trial expense, $1.0 million in supplies and licensing, and $600,000 in legal and consulting expenses.

General and Administrative Expenses. General and administrative expenses for the six months ended June 30, 2019 were $11.2 million, a decrease of $5.0 million from $16.2 million for the same period in 2018. The decrease was due primarily to reductions of $3.9 million in personnel-related and stock compensation expense, $900,000 in supplies, and $170,000 in legal and consulting expense.

Income Tax Benefit. We did not record any income tax benefit for the six months ended June 30, 2019 and 2018, respectively.

Net Loss. The net loss for the six months ended June 30, 2019 was $20.2 million compared to a net loss of $35.6 million for the same period in 2018. The basic and diluted weighted-average shares of common stock outstanding for the six months ended June 30, 2019 were 37,275,954, resulting in a basic and diluted loss per share of $0.54. For the six months ended June 30, 2018, the basic and diluted weighted-average shares of common stock outstanding were 37,160,334, resulting in basic and diluted loss per share of $0.96.

Liquidity and Capital Resources

As of June 30, 2019, we had cash and cash equivalents of $105.4 million. We have historically funded our operations principally through the private placement of equity securities, public offerings of common stock, and license and milestone payments received under our collaboration agreements. We believe that our cash and cash equivalents on hand will be sufficient to fund our operations through 2021.

With the exception of fiscal year 2014, we have incurred operating losses and an accumulated deficit as a result of ongoing research and development spending since inception. We anticipate that we will continue to generate operating losses as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

We may seek to sell additional equity or debt securities or obtain a credit facility if our available cash and cash equivalents are insufficient to satisfy our liquidity requirements or if we develop additional opportunities to do so. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research and development activities, which could harm our business.

Because of the numerous risks and uncertainties associated with the research and development of our product candidates, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results, and costs of clinical trials for our product candidates, and discovery and development activities related to new product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales, facilities, and distribution costs;
- the cost of manufacturing our product candidates and any products we commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- whether, and to what extent, we are required to repay our outstanding government provided loans;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

We believe that our cash and cash equivalents on hand will be sufficient to fund our operations through 2021.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Six Months Ended June 30,	
	2019	**2018**
Net cash used in operating activities	$ (15,343)	$ (21,612)
Net cash provided by investing activities	9	101
Net cash used in financing activities	(32)	(131)
Net decrease in cash and equivalents	$ (15,366)	$ (21,642)

For the six months ended June 30, 2019 and 2018, we used cash of $15.3 million and $21.6 million, respectively, for our operating activities. The decrease in cash used in operating activities was primarily due to the decrease in research and development activity and changes in working capital for the six months ended June 30, 2019 as compared to the six months ended June 30, 2018.

For the six months ended June 30, 2019 and 2018, our investing activities provided cash of $9,000 and $101,000, respectively. The cash provided by investing activities during the six months ended June 30, 2019 was due to proceeds received from sales of property and equipment of $9,000. The cash provided by investing activities during the six months ended June 30, 2018 was due to proceeds received from sales of property and equipment of $108,000, offset by $7,000 used in the purchase of equipment.

For the six months ended June 30, 2019 and 2018, our financing activities used cash of $32,000 and $131,000, respectively. The cash used in financing activities during the six months ended June 30, 2019 was due to the net payments made on long-term obligations and notes payable of $29,000 and repurchases of common stock of $33,000, offset by the issuance of shares of common stock of $30,000. The cash provided by financing activities during the six months ended June 30, 2018 was primarily due to the issuance of shares of common stock for net proceeds of $236,000, offset by net payments on long-term obligations and notes payable of $104,000, and repurchase of common stock of $263,000.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of June 30, 2019 and December 31, 2018, we had cash and cash equivalents of $105.4 million and $120.7 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

Our long-term debt bears interest at fixed rates. Any change in interest rates would have an immaterial impact on our financial statements.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company’s principal executive officer and principal financial officer have concluded, based on an evaluation of the Company’s disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) or 15d-15(e)) as required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15 that, as of June 30, 2019, the Company’s disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

In connection with the evaluation of the Company’s internal control over financial reporting that occurred during the quarter ended June 30, 2019, which is required under the Securities Exchange Act of 1934 by paragraph (d) of Exchange Rules 13a-15 or 15d-15 (as defined in paragraph (f) of Rule 13a-15),

management determined that there was no change that materially affected or is reasonably likely to materially affect internal control over financial reporting.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York (the Court), captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545 (the Securities Action). Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint asserting claims under the federal securities laws against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian (collectively, the Defendants). The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. On March 29, 2018, the Court dismissed the amended complaint for failure to state a claim, without prejudice, and gave the lead plaintiffs until May 4, 2018 to file any amended complaint attempting to remedy the defects in their claims. On May 4, 2018, the lead plaintiffs filed a second amended complaint asserting claims under the federal securities laws against the Defendants. Like the first amended complaint, the second amended complaint alleges that the Defendants made material false and/or misleading statements or omissions relating to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L that caused losses to the Company's investors. The lead plaintiffs do not quantify any alleged damages in the second amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the second amended complaint on July 31, 2018. On February 13, 2019, the Court dismissed the second amended complaint for failure to state a claim, with prejudice, and closed the case. On March 14, 2019, lead plaintiffs filed a notice of appeal. The briefing on lead plaintiffs' appeal was completed in early July 2019 and oral argument before the Second Circuit Court of Appeals is currently scheduled for the week of October 21, 2019. The Company intends to continue defending the Securities Action vigorously.

On or about April 26, 2017, Ronald Morrow filed a shareholder derivative lawsuit on behalf of the Company in the United States District Court for the Southern District of New York, or the Court, against the Company's Chief Executive Officer Charles J. Link, Jr., the Company's Chief Medical Officer and President Nicholas Vahanian, and Company directors Thomas A. Raffin, Joseph Saluri, Ernest J. Talarico, III, Paul R. Edick, Paolo Pucci, and Lota S. Zoth (collectively, the Morrow Defendants), captioned Morrow v. Link., et al., Case 1:17-cv-03039 (the Morrow Action). The complaint alleges that the Morrow Defendants caused the Company to issue false statements in its 2016 proxy statement regarding risk management and compensation matters in violation of federal securities law. The complaint also asserts state law claims against the Morrow Defendants for breaches of fiduciary duties, unjust enrichment, abuse of control, insider trading, gross mismanagement, and corporate waste, alleging that the Morrow Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L, awarded themselves excessive compensation, engaged in illegal insider trading, and grossly mismanaged the Company. The plaintiff does not quantify any alleged damages in the complaint but seeks restitution for damages to the Company, attorneys' fees, costs, and expenses, as well as an order directing that proposals for strengthening board oversight be put to a vote of the Company's shareholders. The language for such proposals is not specified in the complaint. The plaintiff also contemporaneously filed a statement of relatedness, informing the Court that the Morrow Action is related to Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545. On May 19, 2017, the plaintiff dismissed the Morrow Action without prejudice. Also on May 19, 2017, plaintiffs' counsel in the Morrow Action filed a new shareholder derivative complaint that is substantively identical to the Morrow Action, except that the plaintiff is Rickey Ely. The latter action is captioned Ely v. Link, et al., Case 17-cv-3799, or the Ely Action. By agreement of the parties and order dated June 26, 2017, the Court temporarily stayed the Ely Action until the Securities Action is dismissed or otherwise finally resolved. Under the terms of the stay, the plaintiff in the Ely Action has until March 15, 2019 (30 days after dismissal of the Securities Action with prejudice) to file an amended derivative complaint or rest upon the current derivative complaint. By further agreement of the parties, dated March 15, 2019, the Ely Action will continue to be stayed pending the outcome of the appeal in the Securities Action. If the Securities Action continues to be dismissed in its entirety following its appeal plaintiff in the Ely Action has agreed to withdraw or dismiss the action, with prejudice. The Company disputes the claims in the Ely Action and intends to defend against them vigorously.

Item 1A. RISK FACTORS

RISK FACTORS

Investing in our common stock involves significant risks, some of which are described below. In evaluating our business, investors should carefully consider the following risk factors. These risk factors contain, in addition to historical information, forward-looking statements that involve substantial risks and uncertainties. Our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below. The order in which the following risks are presented is not intended to reflect the magnitude of the risks described. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Business Risks

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them. We have not completed testing of any of our product candidates in controlled clinical trials.

The clinical development and regulatory approval process is expensive and time-consuming. The timing of any future product approval cannot be accurately predicted. If we fail to obtain regulatory approval for our current or future product candidates, we will be unable to market and sell them, and therefore we may never be profitable.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required varies depending on the product candidate, the condition being evaluated, the trial results and regulations applicable to any particular product candidate. Any inability to successfully complete preclinical and clinical development could result in additional costs to us.

Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Initial results may not be confirmed upon full analysis of the detailed results of a trial. Product candidates in later-stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

We are heavily dependent on the success of the clinical development of indoximod, and if we fail to complete clinical trials, fail to demonstrate safety and efficacy in those clinical trials, fail to obtain regulatory approval or fail to commercialize indoximod successfully, our business, financial condition and results of operations would be harmed.

The indoximod clinical development program currently encompasses a number of Phase 1 and 2 combination trials across multiple cancer indications. If we fail to complete any of these trials or fail to obtain regulatory approval, our ability to commercialize indoximod will be materially and adversely affected and our business, financial condition and results of operations would be harmed.

If we make changes to any of our product candidates, additional clinical trials may be required resulting in additional costs and delays.

We have an ongoing research program to investigate potential opportunities to improve the potency, efficacy and/or safety profile of some of our product candidates through modifications to their formulations or chemical compositions. These efforts may not be successful. If a new formulation or composition appears promising, we may decide to undertake clinical development of such formulation or composition even if an existing product candidate has shown acceptable safety and efficacy in clinical trials. The nature and extent of additional clinical trials that might be required for a new formulation or composition would depend on many factors. If we were to decide to pursue clinical development of a new formulation or composition, we would incur additional costs and the timeline for

potential commercialization would be delayed. There can be no assurance that any new formulation or composition would prove to be safe or effective or superior to an existing product candidate. Any delay in commercialization of a new formulation or composition may adversely affect our competitive position.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle, including by allowing IND applications to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. Furthermore, our resource allocation decisions and our decisions about whether and how to develop or commercialize any particular product candidate may be based on evaluations of the scientific and commercial potential or target market for the product candidate that later prove to be materially inaccurate. If we enter into collaborations, licensing or other royalty arrangements to develop or commercialize a particular product candidate, we may relinquish valuable rights to that product candidate in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

We may face delays in completing our clinical trials, or we may not be able to complete them at all.

We have not completed all of the clinical trials necessary to support an application with the FDA for approval to market any of our product candidates. Our current and future clinical trials may be delayed or terminated as a result of many factors, including:

- we may experience delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- we may need to reformulate or change the dosing of our product candidates;
- our clinical trials may have slower than expected patient enrollment or lack of a sufficient number of patients that meet their enrollment criteria;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;
- we may experience difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our clinical trial protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials;
- our third-party contractors, including those manufacturing our product candidates or components of ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- we may experience governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines;

- enrollment in and conduct of our clinical trials may be adversely affected by the regulatory approval of competing agents in this class, competition with ongoing clinical trials or scheduling conflicts with participating clinicians; and
- we may experience delays in achieving clinical trial endpoints and completing data analysis for a trial.

In addition, we rely on academic institutions, physician practices and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other aspects of these clinical trials than if we conducted the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol or applicable regulations. We also may rely on clinical research organizations to perform our data management and analysis. They may not provide these services as required or in a timely or compliant manner.

Moreover, our development costs will increase if we are required to complete additional or larger clinical trials for our product candidates prior to FDA approval. If the delays or costs are significant, our financial results and ability to commercialize our product candidates will be adversely affected.

If we encounter difficulties enrolling patients in our clinical trials, our clinical trials could be delayed or otherwise adversely affected.

Clinical trials for our product candidates require us to identify and enroll a large number of patients with the disease under investigation, or healthy volunteers willing to participate in certain trials. We may not be able to enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a clinical trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- changes in the standard of care that make the trial as designed less attractive to clinicians and patients;
- availability of competing therapies and clinical trials, including announced clinical trials evaluating potentially competing IDO pathway inhibitors in clinical settings similar to our clinical trials;
- the results of clinical trials of other IDO pathway inhibitors;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Regulatory authorities may not approve our product candidates even if they meet safety and efficacy endpoints in clinical trials.

We have discussions with and obtain guidance from regulatory authorities regarding certain aspects of our clinical development activities. These discussions are not binding commitments on the part of regulatory authorities. Under certain circumstances, regulatory authorities may revise or retract previous guidance during the course of our clinical activities or after the completion of our clinical trials. A regulatory authority may also disqualify a clinical trial in whole or in part from consideration in support of approval of a potential product for commercial sale or otherwise deny approval of that product. Prior to regulatory approval, a regulatory authority may elect to obtain advice from outside experts regarding scientific issues and/or marketing applications under a regulatory authority review. In the United States, these outside experts are convened through the FDA's Advisory Committee process,

which would report to the FDA and make recommendations that may differ from the views of the FDA. The FDA is not bound by the recommendations of an Advisory Committee, but it typically follows such recommendations. In addition, should an Advisory Committee be convened, it would be expected to lengthen the time for obtaining regulatory approval, if such approval is obtained at all.

The FDA and other foreign regulatory agencies can delay, limit or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- our manufacturing processes or facilities may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional work on our part.

Any delay in, or failure to receive or maintain, approval for any of our product candidates could prevent us from ever generating meaningful revenues or achieving profitability in future years.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may change requirements for approval even after a clinical trial design has been approved. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

Under the Merck Agreement, we have ongoing obligations related to the development of our Ebola vaccine product candidate, which may result in greater costs and a longer timeframe for regulatory approval than we estimate, yet we will receive limited revenues, if any, from any future sales of our Ebola vaccine product candidate.

Under the Merck Agreement, we have ongoing obligations related to the development of our Ebola vaccine product candidate, including obligations related to clinical trials, government contracting and licensing of the vaccine technology, which may cause us to incur costs or losses materially larger than we expect. However, because we have exclusively licensed the right to research, develop, manufacture and distribute our Ebola vaccine product candidate to Merck and we are only entitled to certain royalty and other payments under the Merck Agreement, we will receive limited revenues, if any, even if we or Merck are successful in developing and commercializing our Ebola vaccine product candidate.

The time and cost of product development and the timeframe for regulatory approval of any Ebola vaccine product candidate are uncertain and may be longer and more costly than we estimate. Our Ebola vaccine product candidate is a live virus based on vesicular stomatitis virus (VSV). There are no commercial vaccines based upon this virus, and unforeseen problems related to the use of our live virus vaccine may prevent or materially increase costs and delays of further development or approval of our Ebola vaccine product candidate. There may be unknown safety risks associated with the vaccine, and regulatory agencies such as the FDA may require us to conduct extensive safety testing prior to approval to demonstrate a low-risk of rare and severe adverse events caused by the vaccine.

Public perception of vaccine safety issues, including adoption of novel vaccines based upon VSV, may adversely influence willingness of subjects to participate in clinical trials, or if approved, of physicians to prescribe, and of patients to receive, novel vaccines. For example, our Ebola vaccine product candidate is currently being developed for the prevention of, and may later be developed for the treatment of patients infected with, Ebola, and public aversion to vaccines for Ebola or vaccines in general may adversely influence later-stage clinical trials of this product candidate or, if approved, its commercial success.

Even if approved, a number of factors may adversely affect commercial sales. Lack of familiarity with the viral vaccine and potential adverse events associated with vaccination may adversely affect physician and patient perception and uptake of our potential product. Furthermore, there are no assurances that the vaccine will be approved for inclusion in government stockpile programs, which may be material to the commercial success of the product candidate, either in the United States or abroad. If our Ebola vaccine product candidate eventually is approved and sold commercially, we will receive limited revenues under the Merck Agreement. Finally, in certain cases, our obligations to pay royalties to PHAC may exceed the royalties we receive from Merck.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's Good Clinical Practice (GCP) requirements, or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and Institutional Review Boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under current Good Manufacturing Practice (cGMP) requirements and may require large numbers of test subjects. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- the product candidate may have unforeseen adverse side effects;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- failure to demonstrate a benefit from using a drug;
- the quality or stability of the product candidate may fall below acceptable standards; or
- insufficient quantities of the product candidate to complete the trials.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors indoximod, NLG802, NLG207, NLG919, and other product candidates could take significantly longer to gain regulatory approval than we expect or we may never gain approval for additional indications, which could reduce our revenue by delaying or terminating their commercialization.

Some of our product candidates have been studied, or in the future may be studied, in clinical trials co-sponsored by organizations or agencies other than us, or in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.

We supplied indoximod in support of a Phase 2 investigator-initiated clinical trial, and we provided clinical supply of dorgenmeltucel-L in support of a Phase 2 investigator-initiated clinical trial. Our Ebola vaccine product candidate was studied in clinical trials in West Africa. We may continue to supply and otherwise support similar trials in the future. However, because we are not the sponsors of these trials, we do not control the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment, and, as a result, are subject to risks associated with the way these types of trials are conducted, in particular should any problems arise. These risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data.

If we cannot demonstrate the safety of our product candidates in preclinical and/or other non-clinical studies, we will not be able to initiate or continue clinical trials or obtain approval for our product candidates.

In order to move a product candidate not yet being tested in humans into a clinical trial, we must first demonstrate in preclinical testing that the product candidate is safe. Furthermore, in order to obtain approval, we must also demonstrate safety in various preclinical and non-clinical tests. We may not have conducted or may not conduct in the future the types of preclinical and other non-clinical testing ultimately required by regulatory authorities, or future preclinical tests may indicate that our product candidates are not safe for use in humans. Preclinical testing is expensive, can take many years and can have an uncertain outcome. In addition, success in initial preclinical testing does not ensure that later preclinical testing will be successful. We may experience numerous unforeseen events during, or as a result of, the preclinical testing process, which could delay or prevent our ability to develop or commercialize our product candidates, including:

- our preclinical testing may produce inconclusive or negative safety results, which may require us to conduct additional preclinical testing or to abandon product candidates that we believed to be promising;
- our product candidates may have unfavorable pharmacology, toxicology or carcinogenicity;

- our product candidates may cause undesirable side effects; and
- the FDA or other regulatory authorities may determine that additional safety testing is required.

Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition and results of operations.

Even if ultimately approved, indoximod, NLG802, NLG207, NLG919, our Ebola vaccine product candidate or any other potential product we or our collaborators may commercialize and market may be later withdrawn from the market or subject to promotional limitations.

We or our collaborators may not be able to obtain the labeling claims necessary or desirable for the promotion of any potential future products. We or our collaborators may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory, the FDA or a comparable agency in a foreign country may withdraw marketing authorization or may condition continued marketing on commitments from us or our collaborators that may be expensive and/or time-consuming to fulfill. In addition, if we or others identify adverse side effects after any of our potential products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our potential products, additional clinical trials, changes in labeling of our potential products and/or additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of our potential products.

We will need to develop or acquire additional capabilities in order to commercialize any product candidates that obtain FDA approval, and we may encounter unexpected costs or difficulties in doing so.

We will need to acquire additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. Currently, we have limited experience in preparing applications for marketing approval, commercial-scale manufacturing, managing large-scale information technology systems or managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources.

To do this effectively, we must:

- train, manage and motivate a growing employee base;
- accurately forecast demand for our products; and
- expand existing operational, financial and management information systems.

We will need to increase our manufacturing capacity, which may include negotiating and entering into additional third-party agreements to meet our commercial manufacturing requirements.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate significant product revenue.

We do not have a sales organization and have no experience in the sales and distribution of pharmaceutical products. There are risks involved with establishing our own sales capabilities and increasing our marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us could potentially be lower than if we market and sell these products ourselves.

We entered into the Merck Agreement in November 2014 for the research, development, manufacture and distribution of our Ebola vaccine product candidate. Even if our Ebola vaccine product candidate is approved by regulators for marketing and sale, Merck may be unsuccessful in its efforts to commercialize our Ebola vaccine product candidate, respectively, or may devote fewer resources to such efforts than we would consider optimal.

We may establish our own specialty sales force and/or engage other biopharmaceutical or other healthcare companies with established sales, marketing and distribution capabilities to sell, market and distribute any future products. We may not be able to establish a specialty sales force or establish sales, marketing or distribution relationships on acceptable terms. Factors that may inhibit our efforts to commercialize any future products without strategic collaborators or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to an adequate number of physicians to educate them about the attributes of any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Because the establishment of sales, marketing and distribution capabilities depends on the progress toward commercialization of our product candidates, and because of the numerous risks and uncertainties involved with establishing those capabilities, we are unable to predict when, if ever, we will establish our own sales, marketing and distribution capabilities. If we are not able to collaborate with third parties and are unsuccessful in recruiting sales, marketing and distribution personnel or in building the necessary infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

Failure to attract and retain key personnel could impede our ability to develop our products and to obtain new collaborations or other sources of funding.

Because of the specialized scientific nature of our business, our success is highly dependent upon our ability to attract and retain qualified scientific and technical personnel, consultants and advisors. We are highly dependent on the principal members of our scientific and management staff. Effective August 3, 2019 Charles J. Link, Jr., our founder and former Chief Executive Officer, Chief Scientific Officer and Chairman of the Board, retired from his posts as Chairman, Chief Executive Officer and Chief Scientific Officer and as a member of the Board of Directors of the Company. This change, or the long-term loss of services of any other key executives, might significantly delay or prevent the achievement of our research, development, and business objectives. We do not maintain key-man life insurance with respect to any of our employees, nor do we intend to secure such insurance.

We will need to recruit additional personnel in order to achieve our operating goals. In order to pursue product development and marketing and sales activities, if any, we will need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales. We also rely on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on acceptable terms, if at all. Additionally, our most significant facility is located in Iowa, which may make attracting and retaining qualified scientific and technical personnel from outside of Iowa difficult. The failure to attract and retain qualified personnel, consultants and advisors could have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to Manufacturing Activities

We rely on third-party manufacturers to produce our preclinical and clinical product candidate supplies and we intend to rely on third parties to produce commercial supplies of any product candidates that may be approved in the future. Any failure by a third-party manufacturer to produce supplies for us may delay or impair our ability to complete our clinical trials or commercialize our product candidates.

We do not possess all of the capabilities to fully commercialize any of our product candidates on our own. If we are unable to arrange for third-party manufacturing sources or to do so on commercially reasonable terms, we may not be able to complete development of such product candidates or market them. In addition, we currently rely on our partner Merck for the supply of our Ebola vaccine product candidate and other third party manufacturers for our supply of indoximod, NLG802, NLG207, and NLG919 for preclinical and clinical studies. Problems with any of our facilities or processes, or our contract manufacturers' facilities or processes, could prevent or delay the production of adequate supplies of indoximod, NLG802, NLG207, NLG919, our Ebola vaccine product candidate or other finished products.

Any prolonged delay or interruption in the operations of our current or future contract manufacturers' facilities could result in cancellation of shipments, loss of components in the process of being manufactured or a shortfall in the availability of a product. A number of factors could cause interruptions, including the inability of a supplier to provide raw materials, equipment malfunctions or failures, damage to a facility due to natural disasters, changes in

international or U.S. regulatory requirements or standards that require modifications to our manufacturing processes, action by regulatory authorities or by us that results in the halting or slowdown of production of components or finished product due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified production capacity and sufficiently trained or qualified personnel may not be available on a timely or cost-effective basis or at all. Difficulties or delays in our contract manufacturers' production of product candidates could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue and market share if we are unable to meet market demand for any products that are approved for sale on a timely basis.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, failure of the third party to accept orders for supply of drug substance or drug product and the possibility of termination or nonrenewal of the agreement by the third-party based on its own business priorities and at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes as needed, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates that may have been granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture our product candidates. Such suppliers may not sell this capital equipment or these raw materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of this capital equipment or these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Because of the complex nature of many of our early-stage compounds and product candidates, our manufacturers may not be able to manufacture such compounds and product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize related products. If we successfully commercialize any of our product candidates, we may be required to establish or access large-scale commercial manufacturing capabilities. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. To meet our projected needs for commercial manufacturing in the event that one or more of our product candidates gains marketing approval, third parties with whom we currently work will need to increase their scale of production or we will need to secure alternate suppliers.

Furthermore, we do not currently have experience with the management of relationships related to commercial-scale contract manufacturing, and we may incur substantial costs to develop the capability to negotiate and enter into relationships with third-party contract manufacturers.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our products.

All entities involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our Company, our existing contract manufacturers and those we may engage in the future, and Merck in its capacity as our licensee, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP regulations. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of

our third party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of any of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. In addition, to the extent that we rely on foreign contract manufacturers, as we do currently for our Ebola vaccine product candidate, we are or will be subject to additional risks including the need to comply with export and import regulations.

If our current or future contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

Our facility is located in areas where floods and tornados are known to occur, and the occurrence of a flood, tornado or other catastrophic disaster could damage our facilities and equipment, which could cause us to curtail or cease operations.

Our primary facility is located in Ames, Iowa, which is susceptible to floods and tornados, and our facility is therefore vulnerable to damage or disruption from floods and tornados. We are also vulnerable to damage from other types of disasters, such as power loss, fire and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We currently carry business insurance (real, personal and business income) of approximately $14.4 million in the aggregate, but this policy does not cover disasters such as floods and earthquakes. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our information technology infrastructure, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber-attacks. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent the adverse effect of such events. Significant disruptions of our information technology systems or breaches of data security could adversely affect our business.

Risks Relating to Regulation of Our Industry

The industry within which we operate and our business are subject to extensive regulation, which is costly and time-consuming and which may subject us to unanticipated delays.

The research, development, testing, manufacturing, labeling, packaging, marketing, distribution, promotion and advertising of biologic and pharmaceutical products such as our product candidates are subject to extensive regulation by governmental regulatory authorities in the United States and other countries. The drug development and approval process is generally lengthy, expensive and subject to unanticipated delays. Data obtained from preclinical and clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the

period of development and regulatory review of each submitted application for approval. To obtain approval for a product candidate, we must demonstrate to the satisfaction of the regulatory authorities that the product candidate is safe and effective in the case of a small-molecule pharmaceutical product, or is safe, pure and potent in the case of a biologic, which typically takes several years or more depending upon the type, complexity and novelty of the product and requires the expenditure of substantial resources.

There can be no assurance that we will not encounter problems in clinical trials that would cause us or the regulatory authorities to delay or suspend clinical trials. Any such delay or suspension could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that we will not encounter problems in clinical trials that would cause us or the regulatory authorities to delay or suspend clinical trials. Any such delay or suspension could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that clinical trials for any of our product candidates currently under development will be completed successfully or within any specified time period, if at all. Further, there can also be no assurance that such testing will show any product to be safe, pure, potent or effective. We cannot predict when, if ever, we might submit for regulatory review our product candidates currently under development. In addition, regardless of how much time and resources we devote to the development of a product candidate, there can be no assurance that regulatory approval will be obtained for that product candidate.

Even if such regulatory approval is obtained, we, our products and any contract manufacturers or commercial collaborators of ours will be subject to continual regulatory review in both the United States and other countries. Later discovery of previously unknown problems with regard to a product, distributor or manufacturer may result in restrictions, including withdrawal of the product from the market and/or disqualification or decertification of the distributor or manufacturer. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- warning letters;
- civil or criminal penalties;
- injunctions;
- suspension of or withdrawal of regulatory approval;
- total or partial suspension of any ongoing clinical trials or of production;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of new biologic and pharmaceutical products through lengthy and detailed preclinical and clinical testing procedures, sampling activities and other costly and time-consuming compliance procedures. Clinical trials are vigorously regulated and must meet requirements for FDA review and oversight and requirements under GCP guidelines. A new drug may not be marketed in the United States until the FDA has approved it. There can be no assurance that we will not encounter delays or rejections or that the FDA will not make policy changes during the period of product development and FDA regulatory review of each submitted biologics license application (BLA) and new drug application (NDA). A delay in obtaining, or failure to obtain, such approvals would have a material adverse effect on our business, financial condition and results of operations. Even if regulatory approval were obtained, it would be limited as to the indicated uses for which the product may be promoted or marketed. A marketed product, its manufacturer and the facilities in which it is manufactured are subject to continual review and periodic inspections. If marketing approval is granted, we would be required to comply with FDA requirements for manufacturing, labeling, advertising, record-keeping and reporting of adverse experiences and other information. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label, although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications. Companies may also share truthful and not misleading information that is otherwise consistent with the labeling. In addition, we

would be required to continue to comply with federal and state anti-kickback and other healthcare fraud and abuse laws that pertain to the marketing of pharmaceuticals, among other things. Failure to comply with regulatory requirements and other factors could subject us to regulatory or judicial enforcement actions, including product recalls or seizures, injunctions, withdrawal of the product from the market, civil penalties, criminal prosecution, refusals to approve new products and withdrawals of existing approvals, as well as enhanced product liability exposure, any of which could have a material adverse effect on our business, financial condition and results of operations. Sales of our products outside the United States will be subject to foreign regulatory requirements governing clinical trials, marketing approval, manufacturing and pricing. Noncompliance with these requirements could result in enforcement actions or penalties or could delay the introduction of our products in certain countries.

The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement outside the United States vary greatly from country to country. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Foreign regulatory authorities could also require additional testing. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our products and may have a material adverse effect on our results of operations and financial condition.

We are also subject to laws generally applicable to businesses including, but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistleblowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistleblowing claim, even if without merit, could result in costly litigation or regulatory action or otherwise harm our business, results of operations, financial condition, cash flow and future prospects.

The availability of coverage and amount of reimbursement for our product candidates, if approved, and the manner in which government and private payers may reimburse for our potential products, are uncertain.

In both the United States and foreign markets, sales of our proposed products will depend in part on the availability of coverage and reimbursement from third-party payers such as government health administration authorities, private health insurers and other organizations. In addition, the process for determining whether a third party payor will provide coverage for a pharmaceutical typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payer will pay for the product once coverage is approved. Third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. There can be no assurance that our proposed products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Our future levels of revenues and profitability may be affected by the continuing efforts of governmental and third-party payers to contain or reduce the costs of healthcare. We cannot predict the effect that private sector or governmental health care reforms may have on our business, and there can be no assurance that any such reforms will not have a material adverse effect on our business, financial condition and results of operations. Legislation and regulations affecting the pricing of pharmaceuticals may change before any of our proposed products are approved for marketing. Adoption of such legislation could further limit reimbursement for medical products and services. As a result, we may elect not to market future products in certain markets.

Moreover, while we are in clinical trials, we will not be reimbursed for any of our materials used during the clinical trials, however, certain services rendered to clinical trial participants may be reimbursable by third-party payors for standard of care treatment if not otherwise reimbursed under the applicable clinical trial study budget.

The biopharmaceutical industry is subject to significant regulation and oversight in the United States, in addition to approval of products for sale and marketing; our failure to comply with these laws could harm our results of operations and financial condition.

In addition to FDA restrictions on marketing of biopharmaceutical products, our operations may be directly, or indirectly through our relationships with healthcare providers, customers and third-party payers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute. These laws

may impact, among other things, our proposed sales, and education programs, and these laws have been applied to restrict certain marketing practices in the biopharmaceutical industry. In addition, we may be subject to patient privacy regulation by both the U.S. federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, among others, the following:

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.
- The federal civil False Claims Act prohibits any person or entity from knowingly presenting, or causing to be presented, to the federal government a claim for payment or approval that is false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Several pharmaceutical and other health-care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of off-label promotion. Private parties may initiate qui tam whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit.
- The federal Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA), imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their implementing regulations imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization on covered entities, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information.
- The federal Food, Drug and Cosmetic Act (FDCA) prohibits, among other things, the adulteration or misbranding of drugs and medical devices.
- The federal Physician Payments Sunshine Act, and its implementing regulations require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services (CMS), information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members.
- Analogous state laws and regulations include: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers; state laws that require pharmaceutical companies to comply with the

pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information and that require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. It is possible that some of our business activities could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business, financial condition and results of operations.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that required that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order included a budget neutrality provision that required the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations that can be repealed to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation.

In interim guidance issued by the Office of Information and Regulatory Affairs within the United States Office of Management and Budget on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. Further, on February 24, 2017, President Trump issued an Executive Order requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification. It is difficult to predict how these requirements will continue to be enforced, the extent to which they will continue to impact the FDA's ability to exercise its regulatory authority, and the negative impact they may have on our business.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The U.S. and some foreign jurisdictions are considering or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, in the United States, the pharmaceutical industry has been affected by the passage of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the ACA), which, among other things, imposed new fees on entities that manufacture or import certain branded prescription drugs and expanded pharmaceutical manufacturer obligations to provide discounts and rebates to certain government programs. There have been judicial and congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to

delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (the BBA) among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Although the Texas U.S. District Court Judge, as well as the presidential administration and CMS have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, there has been particular and increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices in recent years, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. There have been several recent U.S. Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While some of the existing measures and other proposed measures will require authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2010. This final rule codified CMS's policy change that was effective January 1, 2019. Any of these initiatives could harm our ability to generate revenues.

In the future, there will likely continue to be proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of drug products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Individual states are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payers or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding

procedures to determine which pharmaceutical products and suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last 10 years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (the Right to Try Act) was signed into law. The law, among other things, provides a federal framework for certain patients to access certain IND products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislative or administrative action, either in the United States or abroad.

We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

Our research and development involves the controlled use of hazardous materials, chemicals, various active microorganisms and volatile organic compounds, and we may incur significant costs as a result of the need to comply with numerous laws and regulations. We are subject to laws and regulations enforced by the FDA, the Drug Enforcement Agency, foreign health authorities and other regulatory requirements, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Food, Drug and Cosmetic Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of our products, materials used to develop and manufacture our product candidates, and resulting waste products. Although we believe that our safety procedures for handling and disposing of such materials, and for killing any unused microorganisms before disposing of them, comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Failure to comply with existing or future data protection laws and regulations related to privacy or data security could lead to government enforcement actions (which could include civil or criminal fines or penalties), private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

Regulation of data processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. We and our partners may be subject to current, new, or modified federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our partners to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our partners' ability to process or use data in order to support the provision of our products or services, or affect our or our partners' ability to offer our products and services in certain locations.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other

personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to civil and/or criminal penalties including if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including, without limitation, the European Union Directive 95/46/EC (the Directive), and the European Union's General Data Protection Regulation (the GDPR) that took effect in May 2018, and member state data protection legislation, may also apply to health-related and other personal information obtained outside of the United States. These laws impose strict obligations on the ability to process health-related and other personal information of data subjects in the European Union, including in relation to use, collection, analysis and transfer of such personal information. These laws include several requirements relating to the consent of the individuals to whom the personal data relates, limitations on data processing, establishing a legal basis for processing, notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, the security and confidentiality of the personal data and various rights that data subjects may exercise.

The Directive and the GDPR prohibits, without an appropriate legal basis, the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions.

Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with European Union data protection laws remains. For example, ongoing legal challenges in Europe to the mechanisms allowing companies to transfer personal data from the EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers, such as the European Union-U.S. and Swiss-U.S. Privacy Shield framework. Additionally, other countries have passed or are considering passing laws requiring local data residency.

Under the GDPR, regulators may impose substantial fines and penalties for non-compliance. Companies that violate the GDPR can face fines of up to the greater of 20 million Euros or 4% of their worldwide annual turnover (revenue). The GDPR has increased our responsibility and liability in relation to personal data that we process, requiring us to put in place additional mechanisms to ensure compliance with the GDPR and other EU and international data protection rules.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations related to security or privacy, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Compliance with data protection laws may be time-consuming, require additional resources and could result in increased expenses, reduce overall demand for our products and services and make it more difficult to meet expectations of our commitments to customers or partners.

Any of these matters could materially adversely affect our business, financial condition, or operational results.

Financial Risks

We have a history of net losses. We incurred a net loss for the years ended December 31, 2016, 2017 and 2018 and expect to continue to incur net losses for the foreseeable future, and we may never achieve or maintain profitability in the future.

We were profitable in the year ended December 31, 2014, primarily as a result of upfront payments under the Genentech Agreement and the Merck Agreement. We are not entitled to receive any additional upfront payments under these licensing or collaboration agreements. We do not expect any milestone or royalty payments under these

or other agreements, if any, to be sufficient to make us profitable in future years. We incurred a loss of $20.2 million for the six months ended June 30, 2019 and we do not expect to be profitable for the foreseeable future. We anticipate that we will continue to incur operating losses over the next several years as we continue our clinical development programs.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities, government grants, economic development loans and capital lease and equipment financing. The size of our future net losses will depend, in part, on the rate of growth or contraction of our expenses and the level and rate of growth, if any, of our revenues. Our ability to achieve profitability in future years is dependent on our ability, alone or with others, to complete the development of our products successfully, obtain the required regulatory approvals, manufacture and market our proposed products successfully or have such products manufactured and marketed by others and gain market acceptance for such products. There can be no assurance as to whether or when we will achieve profitability.

We may require substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

Development of our product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution capabilities, either internally or through collaborations with third parties. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings (including FDA review of any BLA or NDA we file);
- payments required with respect to development milestones we achieve under our in-licensing agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the costs associated with commercializing our product candidates, if they receive regulatory approval;
- the cost of manufacturing our product candidates and any products we commercialize;
- the cost and timing of developing our ability to establish sales and marketing capabilities;
- the potential requirement to repay our outstanding government provided loans;
- competing technological efforts and market developments;
- changes in our existing research relationships;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing and receipt of revenues from existing or future products, if any; and
- payments received under any future strategic collaborations.

We anticipate that we will continue to generate significant losses in the future as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates. We believe that our existing cash and cash equivalents will allow us to fund our operating plan in the near and medium term. However, our operating plan may change as a result of factors currently unknown to us.

There can be no assurance that our revenue and expense forecasts will prove to be accurate, and any change in the foregoing assumptions could require us to obtain additional financing earlier than anticipated. There is a risk of

delay or failure at any stage of developing a product candidate, and the time required and costs involved in successfully accomplishing our objectives cannot be accurately predicted. Actual drug research and development costs could substantially exceed budgeted amounts, which could force us to delay, reduce the scope of or eliminate one or more of our research or development programs.

We are party to license agreements with various parties pursuant to which we have obtained licenses to certain patents, patent applications and other intellectual property related to our product candidates and product development efforts. We are obligated to make aggregate payments ranging from approximately $250,000 to $2.8 million under our license agreements (and in some cases, for each product candidate in such license) upon achievement of development and regulatory approval milestones specified in the applicable license. The timing of our achievement of these events and corresponding milestone payments to our licensors is subject to factors relating to the clinical and regulatory development and commercialization of our product candidates, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization or marketing efforts or seek funds to meet these obligations on terms unfavorable to us.

We may never be able to generate a sufficient amount of product revenue to cover our expenses. Until we do, we expect to seek additional funding through public or private equity or debt financings, collaborative relationships, capital lease transactions or other available financing transactions. However, there can be no assurance that additional financing will be available on acceptable terms, if at all, and such financings could be dilutive to existing stockholders. Moreover, in the event that additional funds are obtained through arrangements with collaborators, such arrangements may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs. Our failure to obtain adequate financing when needed and on acceptable terms would have a material adverse effect on our business, financial condition and results of operations.

Even though we have received governmental support in the past, we may not continue to receive support at the same level or at all.

We have received significant financial assistance, primarily in the form of forgivable loans, from state and local governments. We have also received significant financial assistance, primarily in the form of grants and contracts, from federal agencies to support our infectious disease research. There can be no assurance that we will continue to receive the same level of assistance from these or other government agencies, if at all.

Through our subsidiary, BPS, we have received funding from multiple government agencies for our Ebola vaccine product candidate development efforts. There is no guarantee that we will receive sufficient, or any, future grant funding to meet our obligations related to our Ebola vaccine development or that we or Merck will succeed in developing an Ebola vaccine. The termination of a United States government grant, contract or relationship as a result of our failure to satisfy any of our obligations under the grants or contracts would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, there can be no assurance that we will secure comparable contracts with, or grants from, the United States government in the future.

Changes in our effective income tax rate could adversely affect our results of operations in the future.

For the six months ended June 30, 2019 we have no income tax benefit or expense. Our effective income tax rate, as well as our relative domestic and international tax liabilities, will depend in part on the allocation of any future income among different jurisdictions. In addition, various factors may have favorable or unfavorable effects on our effective income tax rate in individual jurisdictions or in the aggregate. These factors include whether tax authorities agree with our interpretations of existing tax laws, any required accounting for stock options and other share-based compensation, changes in tax laws and rates (including the recently enacted U.S. federal income tax law changes), our future levels of research and development spending, changes in accounting standards, changes in the mix of any future earnings in the various tax jurisdictions in which we may operate, the outcome of any examinations by the U.S. Internal Revenue Service or other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings. The effect on our income tax liabilities resulting from the above-mentioned factors or other factors could have a material adverse effect on our results of operations.

The comprehensive tax reform bill of 2017 could adversely affect our business and financial condition.

On December 22, 2017 the Tax Act was signed into law. The Tax Act significantly revised the Internal Revenue Code of 1986, as amended (the Code) and included, among other things, significant changes to corporate taxation, including a reduction of the corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income for net operating losses arising in taxable years beginning after December 31, 2017 and elimination of net operating loss carrybacks for net operating losses arising in taxable years beginning after December 31, 2017, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act did not have a material impact on our business. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to the Tax Act and the potential tax consequences of investing in or holding our common stock.

Risks Relating to Competition

We compete in an industry characterized by extensive research and development efforts and rapid technological progress. New discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive.

New developments occur and are expected to continue to occur at a rapid pace, and there can be no assurance that discoveries or commercial developments by our competitors will not render some or all of our potential products obsolete or non-competitive, which would have a material adverse effect on our business, financial condition and results of operations.

We expect to compete with fully integrated and well-established pharmaceutical and biotechnology companies in the near and long term. Most of these companies have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. Such companies may succeed in discovering and developing pharmaceutical products more rapidly than we do or pharmaceutical products that are safer, more effective or less costly than any that we may develop. Such companies also may be more successful than we are in production and marketing. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations also conduct clinical trials, seek patent protection and establish collaborative arrangements for the development of oncology products.

We may face competition based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, reimbursement coverage, price and patent position. There can be no assurance that our competitors will not develop safer and more effective products, commercialize products earlier than we do, or obtain patent protection or intellectual property rights that limit our ability to commercialize our products.

There can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide us with proprietary protection or a competitive advantage.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Many of the products that we are attempting to develop and commercialize will be competing with existing therapies. In addition, a number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies both in the United States and abroad. Our competitors may utilize discovery technologies and techniques or collaborate with third parties in order to develop products more rapidly or successfully than we or our collaborators are able to do. Many of our competitors, particularly large pharmaceutical companies, have

substantially greater financial, technical and human resources than we do. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors.

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies, firms specialized in the development and production of vaccines, checkpoint inhibitors, and other immunotherapies, and major universities and research institutions. Many companies have entered into the field of immuno-oncology and are developing or commercializing products in areas that we have targeted for product development. Some of these products use therapeutic approaches that may compete directly with our product candidates. Most of our competitors possess substantially greater financial, technical and human resources than we possess. In addition, many of our competitors have significantly greater experience than we have in conducting preclinical and nonclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of drugs and manufacturing facilities. Accordingly, our competitors may succeed in obtaining regulatory approval for drugs more rapidly than we do. We expect to face growing competition for enrollment of patients in our clinical trials, which could delay or adversely affect our ability to complete such trials. We may also be adversely affected by the clinical trial results of our competitors. For example, if a competitor announces inconclusive or negative clinical trial results with respect to an IDO pathway inhibitor, expectations about IDO pathway inhibitors may be generally impacted and we may experience difficulty in enrolling patients in our indoximod trials. If we obtain regulatory approval and launch commercial sales of our product candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

We also face competition from pharmaceutical and biotechnology companies, academic institutions, government agencies and private research organizations in recruiting and retaining highly qualified scientific personnel and consultants and in the development and acquisition of technologies. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, thereby preventing us from obtaining technology on commercially reasonable terms, if at all. We will also compete for the services of third parties that may have already developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies to target the diseases on which we have focused both inside and outside of the United States.

Our competitive position will also depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often lengthy period between technological conception and commercial sales. We will require substantial capital resources to complete development of some or all of our products, obtain the necessary regulatory approvals and successfully manufacture and market our products. In order to secure capital resources, we may elect to sell additional capital stock, which would dilute the holdings of existing stockholders. We may also attempt to obtain funds through research grants and agreements with commercial collaborators. However, these types of financings are uncertain because they are at the discretion of the organizations and companies that control the funds. Accordingly, we may not receive any additional funds from grants or collaborations.

Research and discoveries by others may result in breakthroughs that render indoximod, NLG802, NLG207, and NLG919 product candidates, or our other potential products obsolete even before they begin to generate any revenue. If the FDA approves the commercial sale of any of our product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited or no experience. We expect that competition among products approved for sale will be based, among other things, on product efficacy, price, safety, reliability, availability, patent protection, and sales, marketing and distribution capabilities. Our profitability and financial position will suffer if our products receive regulatory approval but cannot compete effectively in the marketplace.

Our future products, if any, may not be accepted in the marketplace and therefore, we may not be able to generate significant revenue, or any revenue.

Even if our potential products are approved for sale, physicians and the medical community may not ultimately use them or may use them only in applications more restricted than we expect. Our future products, if successfully developed, will compete with a number of traditional immuno-oncology products manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products will also compete with new products currently under development by such companies and others. Physicians will prescribe a product only if they

determine, based on experience, clinical data, side effect profiles and other factors, that it is beneficial as compared to other products currently in use. Many other factors influence the adoption of new products, including marketing and distribution restrictions, course of treatment, adverse publicity, product pricing, the views of thought leaders in the medical community and coverage and adequate reimbursement by government and private third-party payers.

Risks Relating to Our Arrangements with Third Parties

We rely on third parties to conduct our preclinical studies and our clinical trials. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for our product candidates, or we may be delayed in doing so.

We do not have the ability to conduct preclinical studies or clinical trials independently for our product candidates. We must rely on third parties, such as contract research organizations, medical institutions, academic institutions, clinical investigators and contract laboratories, as well as our strategic collaborators and the third parties that they may use, to conduct our preclinical studies and clinical trials. Other than to the extent that Merck is responsible for clinical trials of our Ebola vaccine product candidate, we are responsible for confirming that our studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with GLP for conducting and recording the results of our preclinical studies and with GCP for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with GCP, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be more costly than expected or budgeted, be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or to commercialize the product candidate being tested in such trials, or may be delayed in doing so.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

We are also dependent on Merck for the development of the product candidates that are the subject of the Merck Agreement. If the company does not succeed in advancing the product candidate to final approval, or decides to discontinue its collaboration with us, such failure or decision, could materially harm our business.

If we fail to enter into any needed collaboration agreements for our product candidates, or if we enter into collaborations that are ultimately unsuccessful, we may be unable to commercialize any potential product effectively or at all.

To successfully commercialize any potential product, we will need substantial financial resources as well as expertise and physical resources and systems. We may elect to develop some or all of these physical resources and systems and expertise ourselves or we may seek to collaborate with another company that can provide some or all of such physical resources and systems as well as financial resources and expertise, as we did in the case of the Genentech Agreement and the Merck Agreement. Such collaborations are complex, and any potential discussions may not result in a definitive agreement for many reasons. For example, whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator’s evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the potential market for the subject product candidates, the costs and complexities of manufacturing and delivering the potential product to patients, the potential of competing products, the existence of uncertainty with respect to ownership or the coverage of our technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. If we were to determine that a collaboration for a potential product is necessary or beneficial and were unable to enter into such a collaboration on acceptable terms, we might elect to delay or scale back the commercialization of the potential product in order to preserve our financial resources or to allow us adequate time to develop the required physical resources and systems and expertise ourselves.

If we enter into a collaboration agreement we consider acceptable, including the Merck Agreement to develop and commercialize our Ebola vaccine product candidate, the collaboration may not proceed as quickly, smoothly or successfully as we plan. The risks in a collaboration agreement include the following:

- the collaborator may not apply the expected financial resources, efforts or required expertise in developing the physical resources and systems necessary to successfully commercialize the subject potential product;
- the collaborator may not invest in the development of a sales and marketing force and the related infrastructure at levels that ensure that sales of the potential product reach their full potential;
- disputes may arise between us and a collaborator that delay the commercialization or adversely affect its sales or profitability of the potential product; or
- the collaborator may independently develop, or develop with third parties, products that could compete with the potential product.

Under the Merck Agreement and any other collaboration for our product candidates, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates, and such disputes may be difficult and costly to resolve or may not be resolved. In addition, a collaborator for the potential product may have the right to terminate the collaboration at its discretion, or to discontinue development of a particular product candidate. For example, in June 2017, Genentech gave notice that it was terminating the Genentech Agreement with respect to NLG919 and gave notice in May 2018 that the remainder of the Agreement would terminate no later than November 6, 2018. Further, Merck has the right to terminate the Merck Agreement for any reason after a specified advance notice period. Any termination may require us to seek a new collaborator, which we may not be able to do on a timely basis, if at all, or may require us to delay or scale back the development or commercialization efforts. The occurrence of any of these events could adversely affect the development or commercialization of the potential product and materially harm our business and stock price by delaying the sale of any product that may be approved by the FDA in the future, by slowing the growth of such sales, by reducing the profitability of the product and/or by adversely affecting the reputation of the product.

We may explore strategic collaborations that may never materialize or may fail.

We may, in the future, periodically explore a variety of possible strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in the process of seeking appropriate strategic collaborators, and such collaborations can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

We are required under the Merck Agreement, and we may be required under other collaborations, to relinquish important rights to and control over the development of our product candidates to our collaborators or otherwise be subject to unfavorable terms.

Our collaborations, including any future strategic collaborations we enter into, could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- other than under the Merck Agreement, we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;

- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may also adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Risks Relating to Protecting Our Intellectual Property

If we are unable to protect our proprietary rights or to defend against infringement claims, we may not be able to compete effectively or operate profitably.

Our success will depend, in part, on our ability to obtain patents, operate without infringing the proprietary rights of others and maintain trade secrets, both in the United States and other countries. Patent matters in the biotechnology and pharmaceutical industries can be highly uncertain and involve complex legal and factual questions. Accordingly, the validity, breadth, and enforceability of our patents and the existence of potentially blocking patent rights of others cannot be predicted, either in the United States or in other countries.

There can be no assurance that we will discover or develop patentable products or processes, or that patents will issue from any of the currently pending patent applications or that claims granted on issued patents will be sufficient to protect our technology or adequately cover the products we may actually sell. Potential competitors or other researchers in the field may have filed patent applications, been issued patents, published articles or otherwise created prior art that could restrict or block our efforts to obtain additional patents. There also can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated, rendered unenforceable or circumvented or that the rights granted thereunder will provide us with proprietary protection or competitive advantages. Our patent rights also depend on our compliance with technology and patent licenses upon which our patent rights are based and upon the validity of assignments of patent rights from consultants and other inventors that were, or are, not employed by us.

In addition, competitors may manufacture and sell our potential products in those foreign countries where we have not filed for patent protection or where patent protection may be unavailable, not obtainable or ultimately not enforceable. In addition, even where patent protection is obtained, third-party competitors may challenge our patent claims in the various patent offices, for example via opposition in the European Patent Office or reexamination or interference proceedings in the United States Patent and Trademark Office (USPTO). The ability of such competitors to sell such products in the United States or in foreign countries where we have obtained patents is usually governed by the patent laws of the countries in which the product is sold.

Merck, which has sublicensed our Ebola vaccine product candidate, has received correspondence from Yale University asserting that it owns certain intellectual property rights with respect to the Ebola vaccine that they assert,

among other things, may need to be licensed by Merck. We also received correspondence from Yale University relating to the research and construction of the Ebola vaccine product by our licensor PHAC. If Merck were required to pay royalties to Yale University, that could result in a reduction of Merck's royalty obligations to us. If Merck otherwise suffered damages as a result of claims by Yale University, it is possible that Merck could seek indemnification from us.

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair our ability to access additional capital and/or cost us significant funds to defend.

We intend to rely on patent rights for our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets.

We rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain regulatory exclusivity and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technologies and product candidates.

We have sought to protect our proprietary position by filing patent applications related to our technologies and product candidates that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable, or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection or data exclusivity, for our product candidates, we may not be able to compete effectively, and our business and results of operations would be harmed.

We may not have sufficient patent term protections for our product candidates to effectively protect our business.

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Additional patent terms may be available through a patent term adjustment process, resulting from the USPTO delays during prosecution. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from generic medications.

Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data exclusivity terms of our product candidates. We

will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our product candidates for an extended period after regulatory approval, if any, which would negatively impact our business, financial condition, results of operations, and prospects. If we do not have sufficient patent terms or regulatory exclusivity to protect our product candidates, our business and results of operations will be adversely affected.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office has developed regulations and procedures to govern administration of the Leahy-Smith Act, but many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first-inventor-to-file provisions, only became effective 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We may be subject to litigation with respect to the ownership and use of intellectual property that will be costly to defend or pursue and uncertain in its outcome.

Our success also will depend, in part, on our refraining from infringing patents or otherwise violating intellectual property owned or controlled by others. Pharmaceutical companies, biotechnology companies, universities, research institutions, and others may have filed patent applications or have received, or may obtain, issued patents in the United States or elsewhere relating to aspects of our technology. It is uncertain whether the issuance of any third-party patents will require us to alter our products or processes, obtain licenses, or cease certain activities. Some third-party applications or patents may conflict with our issued patents or pending applications. Any such conflict could result in a significant reduction of the scope or value of our issued or licensed patents.

In addition, if patents issued to other companies contain blocking, dominating or conflicting claims and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative non-infringing technology and cease practicing those activities, including potentially manufacturing or selling any products deemed to infringe those patents. If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from pursuing the development and commercialization of certain of our potential products. Our failure to obtain a license to any technology that we may require to commercialize our products on favorable terms may have a material adverse impact on our business, financial condition and results of operations.

Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of the proprietary rights of others. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any third party would be found to infringe our patents.

In addition, if our competitors filed patent applications in the United States that claim technology also claimed by us, and such applications were filed before the Leahy-Smith Act took effect, we may have to participate in interference proceedings to determine priority of invention. These proceedings, if initiated by the USPTO, could result in substantial cost to us, even if the eventual outcome is favorable to us. Such proceedings can be lengthy; are costly to defend and involve complex questions of law and fact, the outcomes of which are difficult to predict. An adverse outcome with respect to a third party claim or in an interference proceeding could subject us to significant liabilities, require us to license disputed rights from third parties, or require us to cease using such technology, any of which could have a material adverse effect on our business, financial condition and results of operations.

We also rely on trade secrets to protect technology, especially where patent protection is not believed to be appropriate or obtainable or where patents have not issued. We attempt to protect our proprietary technology and processes, in part, with confidentiality agreements and assignment of invention agreements with our employees and confidentiality agreements with our consultants and certain contractors. There can be no assurance that these

agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We may fail in certain circumstances to obtain the necessary confidentiality agreements, or their scope or term may not be sufficiently broad to protect our interests.

If our trade secrets or other intellectual property becomes known to our competitors, it could result in a material adverse effect on our business, financial condition and results of operations. To the extent that we or our consultants or research collaborators use intellectual property owned by others in work for us, disputes may also arise as to the rights to related or resulting know-how and inventions.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States.

These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries, particularly some developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Relating to Our Exposure to Litigation

We are exposed to potential product liability or similar claims, and insurance against these claims may not be available to us at a reasonable rate in the future.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and commercial sale of human therapeutic products. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper administration of the product candidate, or other factors. Many of these patients are already seriously ill and are therefore particularly vulnerable to further illness or death. In addition, healthy volunteers in our indoximod clinical trial or our Ebola vaccine product candidate clinical trial may suffer, or perceive themselves to suffer, personal injury or death related to the Ebola vaccine product candidates and may initiate legal action against us.

We carried clinical trial liability insurance in the amount of $5.0 million through July 9, 2019 in the aggregate for claims related to our product candidates other than our Ebola vaccine product candidate. We currently carry clinical trial liability insurance in the amount of $10.0 million in the aggregate for claims related to our Ebola vaccine product candidate. We additionally currently carry clinical trial coverage in lower aggregate amounts in local markets where our clinical trials are conducted on a selective, trial by trial basis. There can be no assurance that we will be able to maintain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance. In addition, there can be no

assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any future products by us or our collaborators.

On December 9, 2014, the HHS declared our Ebola vaccine product candidate covered under the Public Readiness and Emergency Preparedness Act. This declaration provides immunity under U.S. law against legal claims related to the manufacturing, testing, development, distribution and administration of our vaccine candidate. It does not generally provide immunity for a claim brought in a court outside the United States.

Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

We are involved in a securities class-action litigation and are at risk of additional similar litigation in the future that could divert management's attention and adversely affect our business and could subject us to significant liabilities.

In the past, securities class action litigation has often been brought against a company following periods of volatility in the market price of securities. We are a party to the securities class action litigation described in Part II, Item 1 of this Quarterly Report on Form 10-Q under the heading "Legal Proceedings." The defense of this litigation may increase our expenses and divert our management's attention and resources and any unfavorable outcome could have a material adverse effect on our business and results of operations. Any adverse determination in this litigation, or any amounts paid to settle this litigation could require that we make significant payments. In addition, we may in the future be the target of other securities class actions or similar litigation.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and could decline significantly.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including those described elsewhere in this "Risk Factors" section of this Quarterly Report on Form 10-Q and the following:

- new products, product candidates or new uses for existing products introduced or announced by our strategic collaborators, or our competitors, and the timing of these introductions or announcements;
- actual or anticipated results from and any delays in our clinical trials, as well as results of regulatory reviews relating to the approval of our product candidates;
- variations in the level of expenses related to any of our product candidates or clinical development programs, including those relating to the timing of invoices from, and other billing practices of, our clinical research organizations and clinical trial sites;
- expenses related to, or our ability or perceived ability to secure, an adequate supply of any future products approved for commercial sale;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures and capital commitments;

- the commercial or clinical success or failure, or perceived success or failure, of our collaborators, including Merck;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- media attention, or changes in media attention, given to cancer and cancer treatment, the recent Ebola epidemic and efforts to develop treatments and vaccines for Ebola, or any other condition or disease that our product candidates are being developed to treat;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- the financial projections we may provide to the public, and any changes in these projections or our failure to meet these projections;
- deviations from securities analysts' estimates or the impact of other analyst rating downgrades by any securities analysts who follow our common stock;
- other events or factors, including those resulting from political uncertainty, war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. We are currently party to the securities class action litigation described in Part II, Item 1 of this Quarterly Report on Form 10-Q under the heading "Legal Proceedings." This litigation and others like it that could be brought against us in the future could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of June 30, 2019, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 39.5% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after June 30, 2019. These stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our Board of Directors, future issuances of our common stock or other securities, declarations of dividends on our common stock and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock. In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares may be distributed and subsequently voted.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to meet compliance obligations.

As a public company, we incur significant legal, accounting and other expenses to comply with reporting requirements of the Securities Exchange Act of 1934 (the Exchange Act), the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), as well as rules subsequently implemented by the SEC and The Nasdaq Global Market. Meeting the requirements of these rules and regulations entails significant legal and financial compliance costs, makes some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel devote a substantial amount of time to these compliance requirements. In addition, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to publish a report by our management on our internal control over financial reporting. To achieve compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which has been both costly and challenging. To maintain compliance on an ongoing basis, we will need to dedicate internal resources, engage outside consultants and adopt a detailed work plan. Despite our effort, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We do not expect to pay any cash dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking only cash dividends should not purchase our common stock.

Provisions in our certificate of incorporation, our by-laws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our certificate of incorporation, our by-laws or Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. These provisions include:

- the division of our Board of Directors into three classes with staggered, three-year terms;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to call special meetings;
- limitations on the ability of stockholders to remove directors or amend our by-laws; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person that together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

The holdings of our stockholders may be diluted, and the prices of our securities may decrease, by the exercise of outstanding stock options or by future issuances of securities by us.

We may issue additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock or the exercise of stock options would dilute existing investors and could adversely affect the price of our securities. In addition, such securities may have rights senior to the rights of securities held by existing investors.

Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Code.

Sections 382 and 383 of the Code limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. A Section 382 ownership change can, therefore, result in significantly greater tax liabilities than a corporation would incur in the absence of such a change, and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

Based on Section 382 ownership change analyses, we believe that, from our inception through December 31, 2017, we experienced Section 382 ownership changes in September 2001 and March 2003, and BPS experienced Section 382 ownership changes in January 2006 and January 2011. These ownership changes limited our ability to utilize federal net operating loss carryforwards and certain other tax attributes that accrued prior to the respective ownership changes of us and our subsidiaries and may continue to limit our ability to utilize such attributes in the future.

Additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders.

Accounting pronouncements may impact our reported results of operations and financial position.

U.S. GAAP and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new pronouncements or the application of existing pronouncements to changes in our business could significantly alter our reported financial statements and results of operations.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following exhibits are filed with this Form 10-Q or incorporated herein by reference to the document set forth next to the exhibit listed below. Where so indicated, exhibits that were previously filed are incorporated by reference.

Exhibit Number	Description	Incorporated By Reference			Filed Herewith
		Form	Filing Date	Number	
3.1	Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2	Certificate of Amendment to Restated Certificate of Incorporation filed on May 10, 2013	8-K	5/14/2013	3.1	
3.3	Amended and Restated Bylaws	8-K	11/18/2011	3.2	
4.1	Form of the Registrant's Common Stock Certificate	S-1/A	10/26/2011	4.1	
4.2	Amended and Restated Investor Rights Agreement by and between the Registrant and certain holders of the Registrant's capital stock dated as of December 1, 2010	10-Q	5/10/2012	4.3	
10.1	Amended and Restated 2009 Equity Incentive Plan				X
31.1	Certification of principal executive officer required by Rule 13a-14(a) / 15d-14(a)				X
31.2	Certification of principal financial officer required by Rule 13a-14(a) / 15d-14(a)				X
32.1#	Section 1350 Certification				X
101.INS‡	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				X
101.SCH‡	XBRL Taxonomy Extension Schema Document				X
101.CAL‡	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF‡	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB‡	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE‡	XBRL Taxonomy Extension Presentation Linkbase Document				X

"The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NewLink Genetics Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing."

‡ Filed herewith electronically.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

NEWLINK GENETICS CORPORATION

By: /s/ Brad J. Powers
Brad J. Powers
General Counsel
(Principal Executive Officer)
Date: August 8, 2019

By: /s/ Carl W. Langren
Carl W. Langren
Chief Financial Officer and Secretary
(Principal Financial Officer)
Date: August 8, 2019

Annex E

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

o **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the quarterly period ended September 30, 2019.

o **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the transition period from to .

Commission File Number
001-35342

NEWLINK GENETICS CORPORATION

(Exact name of Registrant as specified in Its Charter)

Delaware	**42-1491350**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2503 South Loop Drive
Ames, Iowa 50010
(515) 296-5555
(Address, including zip code, and telephone number, including area code, of principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	NLNK	The Nasdaq Stock Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer ☒	Smaller reporting company ☒
Emerging growth company o	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☒

As of October 31, 2019, there were 37,314,076 shares of the registrant’s Common Stock, par value $0.01 per share, outstanding.

NewLink Genetics Corporation

FORM 10-Q

Table of Contents

Page

PART I

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share data)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 98,527	$ 120,738
Prepaid expenses and other current assets	3,311	5,536
Income tax receivable	76	339
Other receivables	740	459
Total current assets	102,654	127,072
Property and equipment, net	2,889	3,727

Right-of-use asset

1,042

—

Income tax receivable

69

140

Total non-current assets

4,000

3,867

Total assets
$
106,654

$
130,939

Liabilities and Stockholders' Equity

Current liabilities:

Accounts payable
$
145

$
555

Accrued expenses

12,125

8,139

Current portion of deferred rent

—

92

Current portion of lease liability

1,712

—

Current portion of notes payable

58

61

Total current liabilities

14,040

8,847

Long-term liabilities:

Royalty obligation payable to Iowa Economic Development Authority

6,000

6,000

Notes payable

—

43

Lease liability

217

—

Deferred rent

—

906

Total long-term liabilities

6,217

6,949

Total liabilities

20,257

15,796	

Stockholders’ equity:

Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at September 30, 2019 and December 31, 2018; issued and outstanding shares — 0 at September 30, 2019 and December 31, 2018	
—	
—	
Common stock, $0.01 par value: Authorized shares — 75,000,000 at September 30, 2019 and December 31, 2018; issued 37,426,844 and 37,343,547 at September 30, 2019 and December 31, 2018, respectively; and outstanding 37,314,076 and 37,251,220 at September 30, 2019 and December 31, 2018, respectively	
373	
373	
Additional paid-in capital	
413,205	
407,199	
Treasury stock, at cost: 112,768 and 92,327 shares at September 30, 2019 and December 31, 2018, respectively	
(1,451)	
(1,417)	
Accumulated deficit	
(325,730)	
(291,012)	
Total stockholders’ equity	
86,397	
115,143	
Total liabilities and stockholders’ equity	
$ 106,654	
$ 130,939	

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating revenues:				
Grant revenue	$ —	$ —	$ —	$ 11,268
Licensing and collaboration revenue	246	120	503	1,004
Total operating revenues	246	120	503	

12,272									
Operating expenses:									
Research and development									
7,024									
7,570									
17,464									
39,972									
General and administrative									
8,279									
7,588									
19,484									
23,792									
Total operating expenses									
15,303									
15,158									
36,948									
63,764									
Loss from operations									
(15,057)									
(15,038)									
(36,445)									
(51,492									

)
Other income and expense:

Miscellaneous (expense) income, net

(33
)

(18
)

(38
)

16

Interest income

567

664

1,815

1,510

Interest expense

(25
)

(2
)

(50
)

(51
)
Other income, net

509

644

1,727

1,475

Net loss before taxes	(14,548)	(14,394)	(34,718)	(50,017)
Income tax benefit	—	6,991	—	6,991
Net loss	$ (14,548)	$ (7,403)	$ (34,718)	$ (43,026)
Basic and diluted loss per share	$ (0.39)	$ (0.20)	$ (0.93)	

$	
(1.16	
)	

Basic and diluted average shares outstanding	
37,308,523	
37,214,363	
37,286,930	
37,178,542	

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
Condensed Consolidated Statement of Stockholders' Equity
(unaudited)
(In thousands, except share data)

Nine Month Period ended September 30, 2019

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2018	37,251,220	$ 373	$ 407,199	$ (1,417)	$ (291,012)	$ 115,143
Share-based compensation	—	—	1,944	—	—	1,944
Restricted stock vested	44,329					

—

—

—

—

—

Repurchase of common stock

(19,447
)

—

—

(32
)

—

(32
)

Net loss

—

—

—

—

(10,036
)

(10,036
)

Balance at March 31, 2019

37,276,102

373

409,143

(1,449
)

(301,048
)

107,019

Share-based compensation

—

—

1,773

—

—

1,773

Restricted stock vested

1,250

—

—

—

—

—

Sales of shares under stock purchase plan

23,967

—

30

—

—

30

Repurchase of common stock

(359
)

—

—

(1
)

—

(1
)
Net loss

—

—

—

(10,134
)

(10,134
)
Balance at June 30, 2019

37,300,960

$
373

$
410,946

$
(1,450
)
$
(311,182
)
$
98,687

Share-based compensation

—

—

2,259

—

—

2,259

Restricted stock vested

13,751

—

—

—

—

—

Repurchase of common stock

(635
)

—

—

(1
)

—

(1
)
Net loss

—

—

—

—

(14,548
)

(14,548
)
Balance at September 30, 2019

37,314,076

373

413,205

(1,451
)

(325,730
)

86,397

	Nine Month Period ended September 30, 2018					
	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2017	37,109,556	$ 372	$ 389,786	$ (1,142)	$ (237,459)	$ 151,557
Share-based compensation	—	—	4,820	—	—	4,820
Restricted stock vested	84,262	1	105	—	—	106
Repurchase of common stock	(28,720)	—	—	(261)	—	(261)
Cumulative effect of accounting change	—	—	—	—	42	42
Net loss	—	—	—	—	(18,310)	(18,310)
Balance at March 31, 2018	37,165,098	373	394,711	(1,403)	(255,727)	137,954
Share-based compensation	—	—	4,177	—	—	4,177
Restricted stock vested	1,250	—	—	—	—	—
Sales of shares under stock purchase plan	32,111	—	130	—	—	130
Repurchase of common stock	(359)	—	—	(2)	—	(2)
Net loss	—	—	—	—	(17,313)	(17,313)
Balance at June 30, 2018	37,198,100	$ 373	$ 399,018	$ (1,405)	$ (273,040)	$ 124,946
Share-based compensation	—	—	4,623	—	—	4,623
Restricted stock vested	19,881	—	33	—	—	33
Repurchase of common stock	(1,089)	—	—	(4)	—	(4)
Net loss	—	—	—	—	(7,403)	(7,403)
Balance at September 30, 2018	37,216,892	$ 373	$ 403,674	$ (1,409)	$ (280,443)	$ 122,195

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2019	**2018**
Cash Flows From Operating Activities		
Net loss	$ (34,718)	$ (43,026)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	5,976	13,620
Depreciation and amortization	432	901
Impairment of fixed assets	351	—
Gain on sale of fixed assets	40	(16)
Amortization of right-of-use asset and change in operating lease liability	(111)	—
Changes in operating assets and liabilities:		

Prepaid expenses and other current assets

2,225

842

Other receivables

(281
)

9,982

Accounts payable and accrued expenses

3,576

(11,749
)
Income taxes receivable

334

(7,042
)
Unearned revenue

—

(56
)
Deferred rent

—

(78
)
Net cash used in operating activities

(22,176
)

(36,622
)
Cash Flows From Investing Activities

Purchase of equipment

—

(7
)
Proceeds on sale of equipment

15

118

Net cash provided by investing activities

15

111

Cash Flows From Financing Activities

Issuance of common stock, net of offering costs

30

269

Repurchase of common stock

(34
)

(267
)
Principal payments on notes payable

(46
)

(138
)
Net cash used in financing activities

(50
)

(136
)
Net decrease in cash and cash equivalents

(22,211
)

(36,647
)
Cash and cash equivalents at beginning of period

120,738

158,708

Cash and cash equivalents at end of period
$

98,527	
$	
122,061	

Supplemental disclosure of cash flows information:

Cash paid for interest	
$ 3	
$ 6	
Cash paid for taxes, net	
$ 14	
$ —	
Cash refunds received for taxes, net	
$ 348	
$ 4	

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Description of Business

On June 4, 1999, NewLink Genetics Corporation (NewLink) was incorporated as a Delaware corporation. NewLink was formed to develop treatments for patients with cancer and other diseases. NewLink initiated operations in April 2000.

NewLink and its subsidiaries (the Company) have historically devoted substantially all of their efforts toward research and development. The Company has never earned revenue from commercial sales of its drugs.

The accompanying condensed consolidated financial statements as of September 30, 2019 and for the three and nine months ended September 30, 2019 have been prepared assuming the Company will continue as a going concern.

The Company's cash and cash equivalents as of September 30, 2019 are expected to be adequate to satisfy the Company's liquidity requirements through 2021. If available liquidity becomes insufficient to meet the Company's operating obligations as they come due, the Company's plans include selling additional shares of common stock, alternative funding arrangements and/or reducing expenditures as necessary to meet the Company's cash requirements. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity. Failure by the Company to successfully execute its plans or otherwise address its liquidity needs may have a material adverse effect on its business and financial position and may materially affect the Company's ability to continue as a going concern.

Proposed Merger with Lumos Pharma

On September 30, 2019, the Company, Cyclone Merger Sub, Inc., a wholly-owned subsidiary of the Company (Merger Sub), and Lumos Pharma, Inc., a privately-held Delaware corporation (Lumos), entered into an Agreement and Plan of Merger and Reorganization (the Merger Agreement), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Lumos, with Lumos surviving as a wholly-owned subsidiary of NewLink (the Merger). Following the Merger, NewLink will change its name to "Lumos Pharma, Inc." and Lumos will change its name to a name mutually agreed upon by the Company and Lumos.

At the effective time of the Merger (Effective Time), each share of Lumos capital stock outstanding immediately prior to the Effective Time (excluding shares of Lumos capital stock held as treasury stock or held or owned by Lumos or Merger Sub prior to the Effective Time and shares held by Lumos stockholders who have exercised and perfected appraisal rights in accordance with Delaware law) shall be automatically converted solely into the right to receive a number of shares of NewLink's common stock equal to the amount determined pursuant to a charter amendment to Lumos' certificate of incorporation that will be filed prior to the Effective Time, at exchange ratios applicable to each type of Lumos capital stock. Pursuant to such conversion, immediately following the Merger, former Lumos stockholders will own approximately 50% of the aggregate number of shares of Company common stock issued and outstanding following the consummation of the Merger (the Post-Closing Shares), and the stockholders of the Company as of immediately prior to the Merger are expected to own approximately 50% of the aggregate number of Post-Closing Shares. Outstanding options to purchase Lumos common stock will be assumed by NewLink and converted into options to purchase a number of shares of NewLink's common stock at the exchange ratio applicable to exchanging shares of Lumos common stock for NewLink's common stock.

The Merger Agreement includes customary representations, warranties and covenants made by the Company and Lumos, including covenants relating to the Company's and Lumos' conduct of their respective businesses between the date of signing the Merger Agreement and the closing of the Merger. Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of the Company and Lumos. Lumos stockholders approved the Merger in September 2019. The Merger Agreement contains certain termination rights for both the Company and Lumos, and further provides that, upon termination of the Merger Agreement under specified circumstances, the Company or Lumos, as applicable, may be required to pay the other party a termination fee of $2.0 million.

The Merger Agreement contemplates that the Company will also seek approval from its stockholders to effect a reverse stock split, with the split ratio to be mutually agreed to by the Company and Lumos immediately prior to the Effective Time. The Merger is expected to close in the first quarter of 2020.

NewLink Genetics Corporation
Notes to Condensed Consolidated Financial Statements
(unaudited)

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared and presented by the Company in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and the rules and regulations of the U.S. Securities and Exchange Commission (the SEC), and, in management's opinion, reflect all adjustments necessary to present fairly the Company's interim condensed financial information.

Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2018, included in the Company's Annual Report on Form 10-K. The financial results for any interim period are not necessarily indicative of financial results for the full year.

3. Significant Accounting Policies

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The condensed consolidated financial statements include the financial statements of NewLink and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Financial Instruments and Concentrations of Credit Risk

Cash and cash equivalents, receivables, and accounts payable are recorded at cost, which approximates fair value based on the short-term nature of these financial instruments. The carrying value of notes payable was $58,000 and $104,000 as of September 30, 2019 and December 31, 2018, respectively, which approximate fair value using Level 2 inputs (computed in accordance with ASC 820). The Company is unable to estimate the fair value of the royalty obligation based on future product sales, as the timing of payments, if any, is uncertain.

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, the Company's cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, the Company invests its excess cash primarily in high-quality securities such as certificates of deposit and money market funds.

Property and Equipment

Property and equipment are capitalized as the Company believes they have alternative future uses and are stated at cost, less accumulated depreciation of $7.6 million and $7.0 million as of September 30, 2019 and December 31, 2018, respectively. Depreciation on all property and equipment is calculated on the straight-line method over the shorter of the lease term or estimated useful life of the asset. Computer equipment has useful lives of three to five years, lab equipment has a useful life of five years, and contract manufacturing organization equipment has a useful life of five years.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02 (Topic 842), Leases, to improve financial reporting for leasing transactions. The Company adopted the standard on January 1, 2019 using the modified retrospective method, as required, applying the new standard to all leases existing as of the date of initial application. The Company has

elected that the date of the initial application, January 1, 2019, will be the effective date. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. The Company elected the "package of practical expedients", which permits the Company not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect to apply the use-of-hindsight or the practical expedient pertaining to land easements; as the latter is not applicable to the Company.

Upon adoption of the standard, the Company recorded a lease liability of $8.5 million and a right of use asset of $7.5 million associated with these leases. Included in the right-of-use asset are lease incentives that were previously recorded as deferred rent liability of $1.0 million as of December 31, 2018 on the consolidated balance sheet. There was no material impact to the consolidated statement of operations. Refer to Note 7 within for additional discussion around the lease liability and right of use asset as of September 30, 2019.

4. Revenues

Revenue Recognition

Revenues are recognized under Topic 606 when control of the promised goods or services is transferred to the Company's customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Prior to transferring the government contracts over to Merck Sharp & Dohme Corp. (Merck) in June 2018, the Company received payments from government entities under its grants and contracts with the Department of Defense and the United States Department of Health and Human Services (HHS). These agreements provided the Company cost reimbursement plus a percentage for certain types of expenditures in return for research and development activities over a contractually defined period. Grant revenues were recognized over time and measured using the input method. The Company used labor costs and subcontractor fees as inputs to measure progress towards satisfying its performance obligations under these agreements. Under this method, the Company recognized revenue generally in the period during which the related costs were incurred, in an amount that reflected the consideration the Company expected to be entitled to in exchange for those goods or services transferred to the government entities due to the government entities' control over the research and development activities.

The grants and contracts with government entities were fully transferred to Merck as of June 2018. Accordingly, during the nine months ended September 30, 2019, the Company recognized no grant revenue. The Company had $520,000 and $309,000 of receivables relating to the government contracts on the balance sheet as of September 30, 2019 and December 31, 2018, respectively. The Company had $24,000 and $54,000 of accrued expenses for subcontractor fees incurred under the government contracts as of September 30, 2019 and December 31, 2018, respectively.

5. License and Research Collaboration Agreement

Merck Sharp & Dohme Corp.

In November 2014, the Company entered into a licensing and collaboration agreement (the Merck Agreement) with Merck to develop, manufacture and commercialize rVSV-ZEBOV-GP, an Ebola vaccine the Company licensed from the Public Health Agency of Canada (PHAC). Under the terms of the Merck Agreement, the Company granted Merck an exclusive, royalty bearing license to rVSV-ZEBOV-GP and related technology. Under the Merck Agreement, the Company received a $30.0 million non-refundable, upfront payment in December 2014, and a one-time $20.0 million non-refundable milestone payment in February 2015 upon the initiation of the pivotal clinical trial using the current rVSV-ZEBOV-GP vaccine product as one arm of the trial. In addition, the Company can receive escalating royalties on potential commercial sales by Merck of the current product candidate ranging from single digit to double digits on the rVSV-ZEBOV-GP license agreement product sales and escalating royalties on potential commercial sales by Merck of products other than current products within the Company's patent rights ranging from low to high single digit, on increasing levels of annual net sales worldwide. Merck is expected to lead the development of rVSV-ZEBOV-GP and any other rVSV-based viral hemorrhagic fever vaccine product candidates in order to create a marketable product safe for human use.

The Merck Agreement was amended on December 5, 2017 in connection with our entry into an amended and restated PHAC license on December 5, 2017. The amended Merck Agreement absolves our subsidiary, BioProtection

Systems Corporation (BPS), from any future obligation to negotiate or amend the terms of the PHAC license, converts the scope of Merck's sublicense under PHAC's intellectual property rights to be non-exclusive in the Ebola Sudan field of use, and requires Merck to reimburse us in certain circumstances where we may be obligated to pay royalties to PHAC as a result of Merck's product sales but Merck would not otherwise be obligated to pay a royalty to us. On April 26, 2018, the Company entered into an agreement with Merck, the U.S. BioMedical Advanced Research and Development Authority (BARDA), and the Defense Threat Reduction Agency (DTRA) to transfer the government grants from BARDA and DTRA to Merck. The transfer was completed in June 2018 and Merck has replaced the Company as the prime contractor on all such grants.

For the three and nine months ended September 30, 2019, the Company recognized revenues under the amended Merck Agreement of $246,000 and $503,000, respectively, for work the Company performed as a subcontractor of Merck under the government contracts that were transferred to Merck. For the three and nine months ended September 30, 2018, the Company recognized license and collaboration revenue under the amended Merck Agreement of $120,000 and $949,000, respectively, for the reimbursement of costs not covered under government contracts.

6. Common Stock Equity Incentive Plan

2009 Equity Incentive Plan

In April 2000, the stockholders approved the Company's 2000 Equity Incentive Plan (the 2000 Plan), in July 2009, the stockholders approved the Company's 2009 Equity Incentive Plan (the 2009 Plan), and in May 2019, the stockholders approved to amend and extend the Company's 2009 Equity Incentive Plan (the 2019 Plan). Following the approval of the 2019 Plan, no additional stock awards will be granted under the 2009 Plan. Shares that remained available for issuance pursuant to the exercise of options or issuance or settlement of stock awards under the 2009 Plan became available for issuance pursuant to the 2019 Plan and all shares that would have otherwise returned to the 2009 Plan became available for issuance pursuant to the 2019 Plan. Under the provisions of the 2019 Plan, the Company may grant the following types of common stock awards:

- Incentive Stock Options
- Nonstatutory Stock Options
- Restricted Stock Awards
- Stock Appreciation Rights

Awards under the 2019 Plan, as amended, may be made to officers, employees, members of the Board of Directors, advisors, and consultants to the Company. As of September 30, 2019, there were 12,400,653 shares of common stock authorized for the 2019 Plan and 5,271,904 shares remained available for issuance.

The following table summarizes the authorized increases of common stock under the 2009 Plan:

Date Authorized	Authorized Shares Added
May 15, 2010	1,238,095
January 7, 2011	714,285
January 1, 2012	823,649
January 1, 2013	839,407
January 1, 2014	1,062,920
January 1, 2015	1,119,233
January 1, 2016	1,152,565
January 1, 2017	

1,166,546

January 1, 2018

1,484,382

January 1, 2019

1,490,048

The increases in the authorized shares of common stock under the 2009 Plan in 2010 and 2011 were approved by the Company's stockholders. The increases in the authorized shares of common stock under the 2009 Plan in 2012

through 2019 were made pursuant to an "evergreen provision," in accordance with which, on January 1 of each year, from 2013 to (and including) 2019, a number of shares of common stock in an amount equal to 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or such lesser amount of shares (or no shares) approved by the Company's Board of Directors, was added or will be added to the shares reserved under the 2009 Plan.

On May 9, 2019, the Company's stockholders approved an amendment to the 2009 Plan which, among other modifications, included decreasing the automatic annual "evergreen provision" from 4% to 3%, in accordance with which, on January 1 of each year, from 2020 to (and including) 2029, a number of shares of common stock in an amount equal to 3% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or such lesser amount of shares (or no shares) approved by the Company's Board of Directors, was added or will be added to the shares reserved under the 2009 Plan.

2010 Non-Employee Directors' Stock Award Plan

Under the terms of the Company's 2010 Non-Employee Directors' Stock Award Plan (the Directors' Plan) which became effective on November 10, 2011, 238,095 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 161,905 shares of common stock were added to the shares reserved for future issuance under the Directors' Plan. As of September 30, 2019, 268,902 shares remain available for issuance under the Directors' Plan.

2010 Employee Stock Purchase Plan

Under the terms of the Company's 2010 Employee Stock Purchase Plan (the 2010 Purchase Plan), which became effective on November 10, 2011, 214,285 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 185,715 shares of common stock were added to the shares reserved for future issuance under the 2010 Purchase Plan. As of September 30, 2019, 29,542 shares remained available for issuance under the 2010 Purchase Plan.

Share-based Compensation

Share-based compensation expense for the three months ended September 30, 2019 and 2018 was $2.3 million and $4.6 million, respectively. Share-based compensation expense for the nine months ended September 30, 2019 and 2018 was $6.0 million and $13.6 million, respectively. Share-based compensation expense is allocated between research and development and general and administrative expenses within the condensed consolidated statements of operations.

As of September 30, 2019, the total compensation cost related to nonvested option awards not yet recognized was $4.7 million and the weighted-average period over which it is expected to be recognized is 2.7 years.

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Stock Options and Performance Stock Options

The following table summarizes the stock option activity, including options with market and performance conditions and options granted and forfeited in conjunction with the option exchange program, for the nine months ended September 30, 2019:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	7,978,030	$ 11.86	4.5
Options granted	3,753,274	1.77	
Options exercised	—	—	
Options forfeited	(4,696,520)	11.43	
Options expired	(1,318,698)	5.93	

Outstanding at end of period

5,716,086

$
6.96

4.0

Options exercisable at end of period

3,165,770

$
11.09

0.9

The Company estimates the fair value of each stock option grant on the date of grant using a Black-Scholes option pricing model. For stock option grants issued with a market condition, the Company used a Monte Carlo simulation valuation model to determine the grant date fair value.

The following table summarizes the range of assumptions used to estimate the fair value of stock options granted, including those options granted with a market condition, during the nine months ended September 30, 2019:

Risk-free interest rate	1.8% to 2.7%
Expected dividend yield	—%
Expected volatility	77.0% to 86.3%
Expected term (in years)	4 to 7.7
Weighted-average grant-date fair value per share	$1.89

No options were exercised during the nine months ended September 30, 2019. The fair value of awards vested during the nine months ended September 30, 2019 was $2.7 million.

During the nine months ended September 30, 2019, the Company's Board of Directors approved and granted 650,000 shares of equity awards to certain executives with either market or performance conditions. The equity awards had a weighted-average grant date fair value per share of $1.24. The equity awards vest upon the achievement of certain performance conditions. Certain performance conditions relating to the equity awards granted in 2017 were met during the three and nine months ended September 30, 2019 and 79,849 shares vested. None of the targets for 2019 equity awards have been met.

Restricted Stock and Performance Restricted Stock

Restricted stock is common stock that is subject to restrictions, including risks of forfeiture, determined by the planning committee of the Board of Directors in its sole discretion, for as long as such common stock remains subject to any such restrictions. A holder of restricted stock has all rights of a stockholder with respect to such stock, including the right to vote and to receive dividends thereon, except as otherwise provided in the award agreement relating to such award. Restricted stock awards are classified as equity within the consolidated balance sheets. The fair value of each restricted stock grant is estimated on the date of grant using the closing price of the Company's common stock on The Nasdaq Stock Market on the date of grant.

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A summary of the Company's unvested restricted stock, including restricted stock with performance conditions, at September 30, 2019 and changes during the nine months ended September 30, 2019 are as follows:

	Number of restricted stock shares	Weighted average grant date fair value
Unvested at beginning of period	68,585	$ 37.75
Granted	—	—
Vested	(59,330)	38.22
Forfeited/cancelled	—	—
Unvested at end of period	9,255	$ 34.73

As of September 30, 2019, the total remaining unrecognized compensation cost related to restricted stock was approximately $124,963 and is expected to be recognized over a weighted-average period of 0.3 years.

The Company does not have a formal policy regarding the source of shares issued upon exercise of stock options or issuance of restricted stock. The Company expects shares issued to be issued from treasury shares or new shares.

Option Exchange Program

On June 20, 2019, the Company commenced an option exchange program (Option Exchange) for its officers and employees to exchange eligible stock options to purchase up to an aggregate of 5,849,059 shares of the Company's common stock that had been granted to eligible holders, for a lesser number of new stock options with a lower exercise price. Stock options granted prior to December 31, 2018 with an exercise price equal to or greater than $2.97 and held by eligible holders in continuous service through the termination of the Option Exchange were eligible for exchange in the Option Exchange.

The eligible shares were exercisable for a reduced number of shares based on the following exchange ratios:

Exercise Price Range per Share	Number of Outstanding Eligible Options	Exchange Ratio (Surrendered Stock Options to New Stock Options)
$2.97-$10.99	2,725,812	2 to 1
$11.00-$24.99	720,373	3 to 1
$25.00-And Up	468,671	4 to 1

Upon the expiration of the Option Exchange on July 31, 2019, 45 eligible employees and 5 eligible directors had tendered an aggregate of 3,914,856 options, representing 67% of the total eligible options, for 1,720,341 new options to purchase shares of common stock (New Awards). Each New Award was granted on July 31, 2019, pursuant to the Company's 2009 Plan, with an exercise price per share of $1.77 per share, the closing price on the grant date of the New Awards. Each New Award has a maximum term of seven years. The New Awards will vest in equal annual amounts over either two or three years, depending on whether the tendered eligible option was vested as of the exchange date.

As a result of this transaction the Company will recognize additional stock-based compensation expense of $1.0 million over the vesting schedule of the New Awards.

7. Leases

The Company has certain facility leases with non-cancellable terms ranging between one and three years, with certain renewal options.

The Company records lease liabilities based on the present value of lease payments over the lease term using an incremental borrowing rate to discount its lease liabilities, as the rate implicit in the lease is typically not readily determinable. To compute the present value of the lease liability, the Company used a weighted-average discount rate of 5%. Certain lease agreements include renewal options that are under the Company's control. The Company

includes optional renewal periods in the lease term only when it is reasonably certain that the Company will exercise its option. Prior to September 30, 2019, the Company had asserted it would renew the lease terms through expiry of the lease renewal option periods. At September 30, 2019, as part of the Company's efforts to reduce costs and conserve resources, the Company concluded it would not be seeking renewal of the leased facilities in Ames, Iowa and upon termination of the lease agreements, it would identify a new space for the Company. As a result of this decision, the Company remeasured the right-of-use assets and lease liabilities using the shorter term. The weighted-average remaining lease term as of September 30, 2019 is 1.0 year.

The Company does not separate lease components from non-lease components. Variable lease payments include payments to lessors for taxes, maintenance, insurance and other operating costs as well as payments that are adjusted based on an index or rate. The Company's lease agreements do not contain any residual value guarantees or restrictive covenants.

Future minimum lease payments under the non-cancellable operating leases (with initial or remaining lease terms in excess of one year) as of September 30, 2019 are as follows (in thousands), excluding option renewals:

For the Year Ended December 31:

2019
$
255

2020

599

2021

133

2022

0

2023

0

Thereafter

0

Total future minimum lease payments

987

Less: Imputed interest

(9
)
Unamortized lease incentive

951

Total
$
1,929

The following table summarizes the aggregate undiscounted non-cancelable future minimum lease payments for operating leases under the prior lease standard as of December 31, 2018 (in thousands), including option renewals:

For the Year Ended December 31:		
2019	$	1,105
2020		1,004
2021		923
2022		906
2023		909
Thereafter		6,570

Total	$ 11,417

8. Income Taxes

For the three and nine months ended September 30, 2019 and 2018, the Company has recorded no and $7.0 million income tax benefit (expense). The income tax amount for the three and nine months ended September 30, 2019 and 2018 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to a full valuation allowance recorded against anticipated net operating loss carryforwards.

The Company has an income tax receivable as of September 30, 2019 for $140,000 of which $71,000 is recorded within short term receivables and $69,000 is recorded in long-term. The full amount was recorded as an income tax benefit in 2017 and is for the receipt of alternative minimum tax (AMT) credit carryovers. The Tax Cuts and Jobs Act of 2017 (the Tax Act), provides that the AMT credit carryovers are partially refundable beginning in 2018 as an offset to a tax liability. The Company expects the amount to be fully refunded by 2021.

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In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of September 30, 2019 and December 31, 2018, respectively, due to the uncertainty of future recoverability.

The Company has a reserve for uncertain tax positions related to state tax matters of $653,000 as of September 30, 2019 recorded within Accrued Expenses in the condensed consolidated balance sheet, which includes the accrual of interest and penalties. The Company does not expect the amount to change significantly within the next 12 months.

9. Net Loss per Share of Common Stock

Basic loss per share is based upon the weighted-average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. Diluted loss per share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average potentially dilutive common stock equivalents during the period when the effect is dilutive.

The following table presents the computation of basic and diluted loss per share of common stock (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Loss attributable to common stockholders	$ (14,548)	$ (7,403)	$ (34,718)	$ (43,026)
Basic and diluted weighted-average shares outstanding	37,308,523	37,214,363	37,286,930	37,178,542
Basic and diluted loss per share	$ (0.39)	$ (0.20)	$ (0.93)	

)
$
(1.16
)

All common stock equivalents are excluded from the computation of diluted loss per share during periods in which losses are reported since the result would be anti-dilutive. As of September 30, 2019, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 5,716,086 and 9,255, respectively. As of September 30, 2018, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 8,371,005 and 89,053, respectively.

10. Restructuring and Severance Charges

The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. Employee severance costs are accrued when the restructuring actions are probable and estimable. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits, is recognized ratably over the future service period. The Company also records costs incurred with contract terminations associated with restructuring activities.

On September 30, 2019, the Company adopted a restructuring plan to reduce its headcount by approximately 60%, which consisted primarily of clinical and research and development staff, and made several changes to senior leadership in order to conserve resources.

In addition to the restructuring, Charles J. Link, Jr, M.D. retired from the Company and the Board of Directors, effective August 3, 2019 and Nicholas Vahanian retired from his position as the President and member of the Board of Directors, effective September 27, 2019, and will remain an employee of the Company through a transition period ending November 11, 2019.

In conjunction with the restructuring and departure of Company executives, the Company recorded restructuring and severance charges of $4.5 million during the three and nine months ended September 30, 2019 of which $2.9 million is included within general and administrative expenses and $1.6 million is included within research and

development expenses. As a result of the restructuring, the Company also recorded an impairment charge of $351,000 relating to fixed assets which management determined had no or limited future use. The fair value of impaired fixed assets was determined based on management's estimate of market resale value.

In July 2018, the Company reduced its headcount by approximately 30% as compared to June 30, 2018 and made several changes to senior leadership effective July 26, 2018 in order to conserve resources to advance its clinical development programs. Restructuring charges of $1.3 million were recorded during the three and nine months ended September 30, 2018.

The following table shows the amount accrued for restructuring and severance activities which is recorded within Accrued Expenses in the condensed consolidated balance sheet (in thousands):

	Employee Severance Cost	Total
Balance as of December 31, 2018	$ 649	$ 649
Expensed	4,489	4,489
Cash Payments	554	554
Balance as of September 30, 2019	$ 4,584	$ 4,584

11. Commitments and Contingencies

From time to time, claims are asserted against the Company arising in the ordinary course of business. In the opinion of management, liabilities, if any, arising from existing claims are not expected to have a material effect on the Company's earnings, financial position, or liquidity.

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York (the Court), captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545 (the Securities Action). Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint asserting claims under the federal securities laws against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian, (collectively, the Defendants). The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. On March 29, 2018, the Court dismissed the amended complaint for failure to state a claim, without prejudice, and gave the lead plaintiffs until May 4, 2018 to file any amended complaint attempting to remedy the defects in their claims. On May 4, 2018, the lead plaintiffs filed a second amended complaint asserting claims under the federal securities laws against the Defendants. Like the first amended complaint, the second amended complaint alleges that the Defendants made material false and/or misleading statements or omissions relating to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L that caused losses to the Company's investors. The lead plaintiffs do not quantify any alleged damages in the second amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the second amended complaint on July 31, 2018. On February 13, 2019, the Court dismissed the second amended complaint for failure to state a claim, with prejudice, and closed the case. On March 14, 2019, lead plaintiffs filed a notice of appeal. The briefing on lead plaintiffs' appeal was completed in early July 2019 and oral argument before the Second Circuit Court of Appeals was held on October 21, 2019. The Company intends to continue defending the Securities Action vigorously.

On or about April 26, 2017, Ronald Morrow filed a shareholder derivative lawsuit on behalf of the Company in the United States District Court for the Southern District of New York, or the Court, against the Company's Chief Executive Officer Charles J. Link, Jr., the Company's Chief Medical Officer and President Nicholas Vahanian, and Company directors Thomas A. Raffin, Joseph Saluri, Ernest J. Talarico, III, Paul R. Edick, Paolo Pucci, and Lota S. Zoth (collectively, the Morrow Defendants), captioned Morrow v. Link., et al., Case 1:17-cv-03039 (the Morrow

Action). The complaint alleges that the Morrow Defendants caused the Company to issue false statements in its 2016 proxy statement regarding risk management and compensation matters in violation of federal securities law. The complaint also asserts state law claims against the Morrow Defendants for breaches of fiduciary duties, unjust enrichment, abuse of control, insider trading, gross mismanagement, and corporate waste, alleging that the Morrow Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L, awarded themselves excessive compensation, engaged in illegal insider trading, and grossly mismanaged the Company. The plaintiff does not quantify any alleged damages in the complaint but seeks restitution for damages to the Company, attorneys' fees, costs, and expenses, as well as an order directing that proposals for strengthening board oversight be put to a vote of the Company's shareholders. The language for such proposals is not specified in the complaint. The plaintiff also contemporaneously filed a statement of relatedness, informing the Court that the Morrow Action is related to Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545. On May 19, 2017, the plaintiff dismissed the Morrow Action without prejudice. Also on May 19, 2017, plaintiffs' counsel in the Morrow Action filed a new shareholder derivative complaint that is substantively identical to the Morrow Action, except that the plaintiff is Rickey Ely. The latter action is captioned Ely v. Link, et al., Case 17-cv-3799, or the Ely Action. By agreement of the parties and order dated June 26, 2017, the Court temporarily stayed the Ely Action until the Securities Action is dismissed or otherwise finally resolved. Under the terms of the stay, the plaintiff in the Ely Action has until March 15, 2019 (30 days after dismissal of the Securities Action with prejudice) to file an amended derivative complaint or rest upon the current derivative complaint. By further agreement of the parties, dated March 15, 2019, the Ely Action will continue to be stayed pending the outcome of the appeal in the Securities Action. If the Securities Action continues to be dismissed in its entirety following its appeal plaintiff in the Ely Action has agreed to withdraw or dismiss the action, with prejudice. The Company disputes the claims in the Ely Action and intends to defend against them vigorously.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and such statements are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information available to our management as of the date hereof. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: the expected completion and timing of the proposed merger with Lumos Pharma; the expected solicitation of and the actual stockholders' approval of issuance of NewLink's common stock pursuant to the merger agreement and reverse stock split; the expected focus of the combined company post consummation of the proposed merger; the development plan for LUM-201; the development plan for our existing pipeline and potential partnership and out-licensing opportunities; our ongoing and planned preclinical studies and clinical trials; the timing of the release of the results of data from ongoing preclinical studies and clinical trials; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the clinical utility of our product candidates; our plans to leverage our existing technologies to discover and develop additional product candidates; our ability to quickly and efficiently identify and develop product candidates; our intellectual property position; the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; plans to develop, commercialize, market and manufacture our product candidates; and other risks and uncertainties, including those described in Part II, Item 1A, "Risk Factors" of this Quarterly Report and in our other periodic reports filed from time to time with the Securities and Exchange Commission, or SEC, including our Annual Report on Form 10-K for the year ended December 31, 2018. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including those risks. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Overview

NewLink Genetics Corporation (the Company, NewLink, we, our or us) is a clinical-stage company that has historically focused on developing novel immunotherapeutic products for the treatment of patients with cancer. Our leading small-molecule product candidates currently in clinical development target the indoleamine-2, 3-dioxygenase (IDO) pathway, which is one of the key pathways for cancer immune escape. These product candidates, indoximod and NLG802 (a prodrug of indoximod), are IDO pathway inhibitors with mechanisms of action that center around breaking the immune system's tolerance to cancer. We also have an additional small molecule product candidate, NLG207 (formerly CRLX101), which is a nanoparticle-drug conjugate (NDC) consisting of a cyclodextrin-based polymer backbone linked to camptothecin, a topoisomerase 1 inhibitor.

Based on early clinical data from our Phase ½ clinical trials, our clinical program to date has been focused on targeted indications with great unmet need where indoximod, NLG802, and NLG207 have produced encouraging early data. Updated Phase 1b data for indoximod for the cohort of pediatric patients with newly diagnosed treatment-naïve diffuse intrinsic pontine glioma (DIPG) has been accepted for presentation at the upcoming ESMO Immuno-Oncology Congress 2019, 11-14 December 2019, Geneva, Switzerland.

Recent Events

On September 30, 2019, we entered into an Agreement and Plan of Merger and Reorganization (the Merger Agreement) with Cyclone Merger Sub, Inc., a wholly-owned subsidiary of NewLink (Merger Sub) and Lumos Pharma, Inc., a privately-held Delaware corporation (Lumos), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into

Lumos, with Lumos surviving as our wholly-owned subsidiary (the Merger). Following the Merger, we will change our name to "Lumos Pharma, Inc." and Lumos will change its name to a name mutually agreed upon by us and Lumos.

At the effective time of the Merger (Effective Time), each share of Lumos capital stock outstanding immediately prior to the Effective Time (excluding shares of Lumos capital stock held as treasury stock or held or owned by Lumos or Merger Sub prior to the Effective Time and shares held by Lumos stockholders who have exercised and perfected appraisal rights in accordance with Delaware law) shall be automatically converted solely into the right to receive a number of shares of our common stock equal to the amount determined pursuant to a charter amendment to Lumos' certificate of incorporation that will be filed prior to the Effective Time, at exchange ratios applicable to each type of Lumos capital stock. Pursuant to such conversion, immediately following the Merger, former Lumos stockholders will own approximately 50% of the aggregate number of shares of our common stock issued and outstanding following the consummation of the Merger (the Post-Closing Shares), and our stockholders as of immediately prior to the Merger will own approximately 50% of the aggregate number of Post-Closing Shares. Outstanding options to purchase Lumos common stock will be assumed by us and converted into options to purchase a number of shares of our common stock at the exchange ratio applicable to exchanging shares of Lumos common stock for our common stock.

The Merger Agreement includes customary representations, warranties and covenants made by the Company and Lumos, including covenants relating to the Company's and Lumos' conduct of their respective businesses between the date of signing the Merger Agreement and the closing of the Merger. Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of the Company and Lumos. Lumos stockholders approved the Merger in September 2019. The Merger Agreement contains certain termination rights for both NewLink and Lumos, and further provides that, upon termination of the Merger Agreement under specified circumstances, NewLink or Lumos, as applicable, may be required to pay the other party a termination fee of $2.0 million.

The Merger Agreement contemplates that we will also seek approval from our stockholders to effect a reverse stock split, with the split ratio to be mutually agreed to by the Company and Lumos immediately prior to the Effective Time. The Merger is expected to close in the first quarter of 2020.

After the consummation of the Merger, the combined company expects to focus its efforts on the development of Lumos' sole product candidate, LUM-201 (ibutamoren), a potential oral therapy for pediatric growth hormone deficiency (PGHD) and other rare endocrine disorders. Our management does not intend to pursue further internal development of its existing pipeline upon consummation of the Merger, but will continue to evaluate our pipeline pending results of the DIPG cohort of our Phase 1b clinical trial for indoximod and, depending on such results, may seek to identify potential partnerships and out-licensing opportunities.

We have prepared this Management's Discussion and Analysis of Financial Condition and Results of Operations and the forward-looking statements contained in this report as if the Merger will not be consummated. If the Merger is consummated, many of the forward-looking statements related to our current product candidates and contained in this report would no longer be applicable.

IDO Pathway Inhibitors

In cancer, the IDO pathway regulates immune response by suppressing T-cell activation, which enables cancer to avoid immune response. IDO is overexpressed in many cancers, both within tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor-draining lymph nodes, thereby promoting peripheral tolerance to tumor associated antigens (TAAs). When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system.

The IDO pathway refers to a series of reactions initiated by IDO that result in the reduction of the amino acid tryptophan in the local tumor environment. We believe the local presence of tryptophan in adequate concentrations promotes antitumor T-cells, and the local reduction of tryptophan combined with the presence of the breakdown product of tryptophan metabolism, kynurenine, is understood to suppress the activation of T-cells. Preclinical and, increasingly, clinical data suggest that IDO pathway inhibitors may also enhance the anti-tumor effects of other immunotherapies, chemotherapies and radiation when used as a combination therapy for patients with cancer.

Currently, we have a clinical development program primarily focused on the IDO pathway. Our small-molecule IDO pathway inhibitor product candidates currently in clinical development include indoximod and NLG802. Our product candidates are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. Indoximod acts as a tryptophan mimetic, thereby signaling the activation of antitumor T-cells by the activation of mammalian target of rapamycin (mTOR), acts directly on T-cells, and modulates aryl hydrocarbon receptor (AhR)-mediated effects.

We have observed an encouraging safety profile for our IDO pathway inhibitors. They are also orally bioavailable and we believe they offer the potential to be synergistic with other therapies such as radiation, chemotherapy, vaccination and immunotherapies involving other checkpoint inhibitors such as anti-PD-1, anti-programmed cell death ligand-1 (PD-L1), or anti-cytotoxic T-lymphocyte antigen 4 (CLTA4). Clinical data suggest an increase in clinical activity without adding significant toxicity.

Indoximod

Indoximod, our lead IDO pathway inhibitor, is currently in clinical development in combination with other cancer therapeutics for patients with DIPG. We believe there may be future opportunities to apply indoximod to a broader set of cancer indications based upon clinical data generated by the Company and potentially resulting from data generated by others with ongoing IDO clinical development programs. More than 900 patients have been treated with indoximod to date and it has generally been well-tolerated, including in combination with PD-1 checkpoint inhibitors, various chemotherapy agents, radiation, and a cancer vaccine.

A tablet formulation of indoximod hydrochloride has been developed for adult patients and a sprinkle formulation is being developed for pediatric indications. We plan to use our new tablet formulation of indoximod in any future clinical trials.

Two U.S. patents covering both the salt and prodrug formulations of indoximod were issued in the U.S. on August 15, 2017 and February 19, 2019 providing exclusivity until at least 2036. We are currently pursuing international patent coverage for these formulations.

NLG802

NLG802 is a prodrug of indoximod. NLG802 is intended to increase bioavailability and exposure to indoximod above levels currently achievable by direct oral administration of indoximod. We filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA), in the first quarter of 2017 and the first patient was dosed with NLG802 in a Phase 1 clinical trial in July 2017. The purpose of this Phase 1 trial is to assess preliminary safety and to determine the recommended dose for subsequent Phase 2 evaluations. NLG802 is a new chemical entity with patent coverage into 2036. We are also pursuing international patent coverage for NLG802.

In May 2019, we presented updated results for the Phase 1 dose escalation trial for NLG802 at the Immuno-Oncology 2019 World Congress. Pharmacokinetics (PK) results were also reported from this study. After continuous twice-daily dosing with NLG802 at all levels, significantly higher PK exposure as compared to indoximod was observed. At 1452 mg twice daily, the highest dose administered, NLG802 produced a 6-fold increase in Cmax and a 4.7-fold increase in AUC compared with molar equivalent indoximod dosing.

The treatment regimen was well tolerated with no NLG802-related serious adverse events reported. The recommended Phase 2 dose was established at 1452 mg BID based on achieving preclinical exposure levels required for pharmacodynamic effects of indoximod.

NLG919

NLG919, a direct IDO enzymatic inhibitor, was previously in clinical development as part of our collaboration with Genentech, Inc. (Genentech). In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech (the Genentech Agreement). The Genentech Agreement provided for the development and commercialization of NLG919. On December 6, 2017, the Genentech Agreement with respect to NLG919 was terminated. As part of the partial termination, worldwide rights to NLG919 reverted to us and Genentech granted us a license under certain of Genentech’s intellectual property to develop and commercialize NLG919. We continue to explore the potential for further development and licensing opportunities but do not have an active program for the drug product candidate as of September 30, 2019.

Additional Product Candidates

NLG207

NLG207 is a NDC consisting of a cyclodextrin-based polymer backbone linked to camptothecin, a topoisomerase-1, or top-1, inhibitor. Because the vasculature in tumors is more permeable than normal tissue, we believe NDCs have the potential to enhance drug delivery to tumors by enabling gradual payload release inside cancer cells to augment antitumor activity while reducing off-target toxicity. NLG207 has been studied in more than 400 patients as monotherapy or in combination with other anticancer agents for patients with solid tumors.

A Phase 2 trial evaluating NLG207 plus paclitaxel for patients with recurrent ovarian, fallopian tube or primary peritoneal cancer was completed in collaboration with the Gynecological Oncology Group and the results of the trial were presented at the annual meeting for the American Association for Cancer Research on April 2, 2019.

We are exploring the potential for further development through out-licensing opportunities for the drug product candidate as of September 30, 2019.

Ebola Vaccine Candidate

In November 2014, we entered into the Merck Agreement to develop and potentially commercialize our rVSVΔG-ZEBOV-GP vaccine product candidate and other aspects of our vaccine technology. The rVSVΔG-ZEBOV-GP vaccine product candidate was originally developed by the Public Health Agency of Canada (PHAC) and is designed to utilize the rVSV vector to induce immunity against Ebola virus when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. Under the Merck Agreement, we received an upfront payment of $30.0 million in October 2014, and in February 2015 we received a milestone payment of $20.0 million. We have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved by the FDA and successfully commercialized by Merck. rVSVΔG-ZEBOV-GP is also eligible to receive a priority review voucher and we are entitled to a portion of the value of the voucher if it is granted. In addition to milestone payments from Merck, we were awarded contracts for development of the rVSVΔG-ZEBOV-GP from the U.S. BioMedical Advanced Research & Development Authority (BARDA), and the Defense Threat Reduction Agency (DTRA), totaling $52.1 million during 2016 and $67.0 million during 2014 and 2015. Funds of $2.1 million were de-obligated from the DTRA grant awards in 2017. We have received total awards of $118.8 million.

On April 26, 2018 we entered into an agreement with Merck, DTRA and BARDA to transfer the government grants from BARDA and DTRA to Merck. The transfer was completed in June 2018 and Merck has replaced us as the prime contractor on all such grants.

Merck announced in September 2019 that the FDA had accepted its biologics license application (BLA) filing and granted priority review for the Ebola vaccination. The Prescription Drug User Fee Act, or target action date, is set for March 14, 2020.

Restructuring Charges

On September 30, 2019, we adopted a restructuring plan to reduce our headcount by approximately 60%, which consisted primarily of clinical and research and development staff, and made several changes to senior leadership in order to conserve resources.

In addition to the restructuring, effective August 3, 2019, Charles J. Link, Jr, M.D. retired from his position as the Chairman, Chief Executive Officer and Chief Scientific Officer and a member of the Board of Directors of the Company, and Nicholas Vahanian retired from his position as the President and member of the Board of the Company, effective September 27, 2019, and will remain an employee of the Company through a transition period ending November 11, 2019.

In conjunction with the restructuring and departure of our executives, we recorded restructuring and severance charges of $4.5 million during the three and nine months ended September 30, 2019 of which $2.9 million is included within general and administrative expenses and $1.6 million is included within research and development expenses. As a result of the restructuring, we also recorded an impairment charge of $351,000 relating to fixed assets for which management determined had no or limited future use. The fair value of impaired fixed assets was determined based on management’s estimate of market resale value.

In July 2018, we reduced our headcount by approximately 30% as compared to June 30, 2018 and made several changes to senior leadership effective July 26, 2018 in order to conserve resources to advance its clinical development programs. Restructuring charges of $1.3 million were recorded during the three and nine months ended September 30, 2018.

Amounts accrued for restructuring and severance activities is recorded within Accrued Expenses in the condensed consolidated balance sheet.

Corporate Information

Founded in 1999, our executive offices are located in the Iowa State University Research Park in Ames, Iowa. We have approximately 50,160 square feet, comprising executive office space and space available for manufacturing, testing and product storage, leased with the Iowa State University Research Park Corporation. At the earlier of the entry into a sublease agreement with a tenant or termination of these lease agreements, with the last to terminate in March 2021, we will seek to lease an office space in the Ames, Iowa area with a smaller footprint. We have additional executive and administrative space in Austin, Texas, with the lease ending in December 2019, and clinical, regulatory and executive offices in Wayne, Pennsylvania.

We incurred a net loss of $34.7 million for the nine months ended September 30, 2019. We expect to continue to incur losses over the next several years as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

Critical Accounting Policies and Significant Judgments and Estimates

We have prepared our financial statements in accordance with U.S. GAAP which requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, expenses and related disclosures at the date of the financial statements, as well as revenues and expenses during the reporting periods. As such, to understand our financial statements, it is important to understand our critical accounting policies. A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Actual results could, therefore, differ materially from these estimates under different assumptions or conditions.

Our Annual Report on Form 10-K for the year ended December 31, 2018 discusses our most critical accounting policies. Since December 31, 2018, there have been no material changes in the critical accounting policies discussed in our 2018 Annual Report.

Recent Accounting Pronouncements

We adopted ASC Topic 842 on January 1, 2019 and have disclosed the impact adoption had on our condensed consolidated financial statements within Note 3 of the "Notes to Condensed Consolidated Financial Statements" of this Form 10-Q. We do not believe that any other recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

Results of Operations

Comparison of the Three Months Ended September 30, 2019 and 2018

Revenues. Revenues for the three months ended September 30, 2019 were $246,000, a increase of $126,000 from $120,000 for the same period in 2018. The increase in revenue was attributable to an increase of $126,000 in licensing revenue, attributable to higher billings to Merck. We recognized licensing revenue during the three months ended September 30, 2019 for work we performed as a subcontractor of Merck.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2019 were $7.0 million, a decrease of $546,000 from $7.6 million for the same period in 2018. The decrease was primarily due to reductions of $1.1 million in personnel-related and stock compensation expense, $255,000 in contract research and manufacturing spend, and $333,000 in legal and consulting and supplies expense, offset by increases of $1.1 million in restructuring and severance expenses and $87,000 in clinical trial and licensing expense.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2019 were $8.3 million, an increase of $691,000 from $7.6 million for the same period in 2018. The increase was due primarily to increases of $2.0 million in restructuring and severance expenses, and $1.2 million in legal and consulting expense, offset by decreases of $1.7 million in stock compensation expense, $431,000 in personnel-related expense, and $353,000 in supplies.

Income Tax Benefit. We recorded no income tax benefit for the three months ended September 30, 2019. We recorded an income tax benefit of $7.0 million for the three months ended September 30, 2018. The income tax benefit differs from the three months ended September 30, 2018 due to a refund received in 2018 as a result of amendments filed to change the allocation of income for certain states for the years ending December 31, 2014 and 2015.

Net Loss. The net loss for the three months ended September 30, 2019 was $14.5 million compared to a net loss of $7.4 million for the same period in 2018. The basic and diluted weighted-average shares of common stock outstanding for the three months ended September 30, 2019 were 37,308,523, resulting in a basic and diluted loss per share of $0.39. For the three months ended September 30, 2018, the basic and diluted weighted-average shares of common stock outstanding were 37,214,363, resulting in basic and diluted loss per share of $0.20.

Comparison of the Nine Months Ended September 30, 2019 and 2018

Revenues. Revenues for the nine months ended September 30, 2019 were $503,000, a decrease of $11.8 million from $12.3 million for the same period in 2018. The decrease in revenue was due to a decrease in grant revenue of $11.3 million, primarily attributable to a decrease in billings under the government grant contracts which were fully transferred to Merck in June 2018, and a decrease of $501,000 in licensing revenue, attributable to lower billings to Merck. We recognized licensing revenue during the nine months ended September 30, 2019 for work we performed as a subcontractor of Merck.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2019 were $17.5 million, a decrease of $22.5 million from $40.0 million for the same period in 2018. The decrease was primarily due to reductions of $12.5 million in contract research and manufacturing spend, $5.2 million in personnel-related and stock compensation expense, $4.0 million in clinical trial expense, $961,000 in supplies and licensing, and $945,000 in legal and consulting expenses, offset by an increase of $1.1 million in restructuring and severance expenses.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2019 were $19.5 million, a decrease of $4.3 million from $23.8 million for the same period in 2018. The decrease was due primarily to reductions of $6.0 million in personnel-related and stock compensation expense, and $1.2 million in supplies expense, offset by increases of $2.0 million in restructuring and severance expenses and $988,000 in legal and consulting expense.

Income Tax Benefit. We recorded no income tax benefit for the nine months ended September 30, 2019 and a $7.0 million income tax benefit for the nine months ended September 30, 2018. The income tax benefit differs from the nine months ended September 30, 2018 due to a refund received in 2018 as a result of amendments filed to change the allocation of income for certain states for the years ending December 31, 2014 and 2015.

Net Loss. The net loss for the nine months ended September 30, 2019 was $34.7 million compared to a net loss of $43.0 million for the same period in 2018. The basic and diluted weighted-average shares of common stock outstanding for the nine months ended September 30, 2019 were 37,286,930, resulting in a basic and diluted loss per share of $0.93. For the nine months ended September 30, 2018, the basic and diluted weighted-average shares of common stock outstanding were 37,178,542, resulting in basic and diluted loss per share of $1.16.

Liquidity and Capital Resources

As of September 30, 2019, we had cash and cash equivalents of $98.5 million. We have historically funded our operations principally through the private placement of equity securities, public offerings of common stock, and license and milestone payments received under our collaboration agreements. We believe that our cash and cash equivalents on hand will be sufficient to fund our operations through 2021.

With the exception of fiscal year 2014, we have incurred operating losses and an accumulated deficit as a result of ongoing research and development spending since inception. We anticipate that we will continue to generate

operating losses to the extent that we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

We may seek to sell additional equity or debt securities or obtain a credit facility if our available cash and cash equivalents are insufficient to satisfy our liquidity requirements or if we develop additional opportunities to do so. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research and development activities, which could harm our business.

Because of the numerous risks and uncertainties associated with the research and development of our product candidates, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results, and costs of clinical trials for our product candidates, and discovery and development activities related to new product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales, facilities, and distribution costs;
- the cost of manufacturing our product candidates and any products we commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- whether, and to what extent, we are required to repay our outstanding government provided loans;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Nine Months Ended September 30,	
	2019	**2018**
Net cash used in operating activities	$ (22,176)	$ (36,622)
Net cash provided by investing activities	15	111
Net cash used in financing activities	(50)	(136)
Net decrease in cash and equivalents	$ (22,211)	$ (36,647)

For the nine months ended September 30, 2019 and 2018, we used cash of $22.2 million and $36.6 million, respectively, for our operating activities. The decrease in cash used in operating activities was primarily due to the decrease in research and development activity and changes in working capital for the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018.

For the nine months ended September 30, 2019 and 2018, our investing activities provided cash of $15,000 and $111,000, respectively. The cash provided by investing activities during the nine months ended September 30, 2019 was due to proceeds received from sales of property and equipment of $15,000. The cash provided by investing activities during the nine months ended September 30, 2018 was due to proceeds received from sales of property and equipment of $118,000, offset by $7,000 used in the purchase of equipment.

For the nine months ended September 30, 2019 and 2018, our financing activities used cash of $50,000 and $136,000, respectively. The cash used in financing activities during the nine months ended September 30, 2019 was due to the net payments made on long-term obligations and notes payable of $46,000 and repurchases of common

stock of $34,000, offset by the issuance of shares of common stock of $30,000. The cash provided by financing activities during the nine months ended September 30, 2018 was primarily due to the issuance of shares of common stock for net proceeds of $269,000, offset by net payments on long-term obligations and notes payable of $138,000, and repurchase of common stock of $267,000.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of September 30, 2019 and December 31, 2018, we had cash and cash equivalents of $98.5 million and $120.7 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

Our long-term debt bears interest at fixed rates. Any change in interest rates would have an immaterial impact on our financial statements.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company's principal executive officer and principal financial officer have concluded, based on an evaluation of the Company's disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, as amended (Exchange Act), Rules 13a-15(e) or 15d-15(e)) as required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15 that, as of September 30, 2019, the Company's disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

In connection with the evaluation of the Company's internal control over financial reporting that occurred during the quarter ended September 30, 2019, which is required under the Exchange Act by paragraph (d) of Exchange Rules 13a-15 or 15d-15 (as defined in paragraph (f) of Rule 13a-15), management determined that there was no change that materially affected or is reasonably likely to materially affect internal control over financial reporting.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York (the Court), captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545 (the Securities Action). Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint asserting claims under the federal securities laws against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian (collectively, the Defendants). The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. On March 29, 2018, the Court dismissed the amended complaint for failure to state a claim, without prejudice, and gave the lead plaintiffs until May 4, 2018 to file any amended complaint attempting to remedy the defects in their claims. On May 4, 2018, the lead plaintiffs filed a second amended complaint asserting claims under the federal securities laws against the Defendants. Like the first amended complaint, the second amended complaint alleges that the Defendants made material false and/or misleading statements or omissions relating to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L that caused losses to the Company's investors. The lead plaintiffs do not quantify any alleged damages in the second amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the second amended complaint on July 31, 2018. On February 13, 2019, the Court dismissed the second amended complaint for failure to state a claim, with prejudice, and closed the case. On March 14, 2019, lead plaintiffs filed a notice of appeal. The briefing on lead plaintiffs' appeal was completed in early July 2019 and oral argument before the Second Circuit Court of Appeals is currently scheduled for the week of October 21, 2019. The Company intends to continue defending the Securities Action vigorously.

On or about April 26, 2017, Ronald Morrow filed a shareholder derivative lawsuit on behalf of the Company in the United States District Court for the Southern District of New York, or the Court, against the Company's Chief Executive Officer Charles J. Link, Jr., the Company's Chief Medical Officer and President Nicholas Vahanian, and Company directors Thomas A. Raffin, Joseph Saluri, Ernest J. Talarico, III, Paul R. Edick, Paolo Pucci, and Lota S. Zoth (collectively, the Morrow Defendants), captioned Morrow v. Link., et al., Case 1:17-cv-03039 (the Morrow Action). The complaint alleges that the Morrow Defendants caused the Company to issue false statements in its 2016 proxy statement regarding risk management and compensation matters in violation of federal securities law. The complaint also asserts state law claims against the Morrow Defendants for breaches of fiduciary duties, unjust enrichment, abuse of control, insider trading, gross mismanagement, and corporate waste, alleging that the Morrow Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L, awarded themselves excessive compensation, engaged in illegal insider trading, and grossly mismanaged the Company. The plaintiff does not quantify any alleged damages in the complaint but seeks restitution for damages to the Company, attorneys' fees, costs, and expenses, as well as an order directing that proposals for strengthening board oversight be put to a vote of the Company's shareholders. The language for such proposals is not specified in the complaint. The plaintiff also contemporaneously filed a statement of relatedness, informing the Court that the Morrow Action is related to Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545. On May 19, 2017, the plaintiff dismissed the Morrow Action without prejudice. Also on May 19, 2017, plaintiffs' counsel in the Morrow Action filed a new shareholder derivative complaint that is substantively identical to the Morrow Action, except that the plaintiff is Rickey Ely. The latter action is captioned Ely v. Link, et al., Case 17-cv-3799, or the Ely Action. By agreement of the parties and order dated June 26, 2017, the Court temporarily stayed the Ely Action until the Securities Action is dismissed or otherwise finally resolved. Under the terms of the stay, the plaintiff in the Ely Action has until March 15, 2019 (30 days after dismissal of the Securities Action with prejudice) to file an amended derivative complaint or rest upon the current derivative complaint. By further agreement of the parties, dated March 15, 2019, the Ely Action will continue to be stayed pending the outcome of the appeal in the Securities Action. If the Securities Action continues to be dismissed in its entirety following its appeal plaintiff in the Ely Action has agreed to withdraw or dismiss the action, with prejudice. The Company disputes the claims in the Ely Action and intends to defend against them vigorously.

Item 1A. RISK FACTORS

RISK FACTORS

Investing in our common stock involves significant risks, some of which are described below. In evaluating our business, investors should carefully consider the following risk factors. These risk factors contain, in addition to historical information, forward-looking statements that involve substantial risks and uncertainties. Our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below. The order in which the following risks are presented is not intended to reflect the magnitude of the risks described. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. Except for the important risk factors relating to consummation of the proposed Merger with Lumos, the following risk factors have been prepared as if the Merger will not be consummated. However, many of the same risks identified below will continue to apply to the combined company if the Merger is consummated.

Risks Related to the Merger

If the proposed Merger with Lumos is not consummated, our business could suffer materially and our stock price could decline.

The consummation of the proposed Merger with Lumos is subject to a number of closing conditions, including the approval by NewLink stockholders and other customary closing conditions. We are targeting a closing of the Merger by the first quarter of 2020.

If the proposed Merger is not consummated, we may be subject to a number of material risks, and our business and stock price could be materially adversely affected, as follows:

- we have incurred and expect to continue to incur significant expenses related to the proposed Merger with Lumos even if the Merger is not consummated;
- the Merger Agreement contains covenants relating to our solicitation of competing acquisition proposals and the conduct of our business between the date of signing the Merger Agreement and the closing of the Merger. Accordingly, we may be unable to pursue business opportunities that would otherwise be in our best interest as a standalone company;
- we may be obligated to pay Lumos a $2.0 million termination fee in connection with the termination of the Merger Agreement;
- our customers, manufacturers, partners and other investors in general may view the failure to consummate the Merger as a poor reflection on our business or prospects;
- some of our manufacturers and other business partners may seek to change or terminate their relationships with us as a result of the proposed Merger;
- as a result of the proposed Merger, current and prospective employees could experience uncertainty about their future roles within the combined company. This uncertainty may adversely affect our ability to retain our key employees, who may seek other employment opportunities;
- our workforce reduction costs may be greater than anticipated and the workforce reduction may have an adverse impact on our development activities;
- our management team may be distracted from day to day operations as a result of the proposed Merger; and
- the market price of our common stock may decline to the extent that the current market price reflects a market assumption that the proposed Merger will be completed.

In addition, if the Merger Agreement is terminated and the NewLink Board determines to seek another business combination, it may not be able to find a third party willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the Merger. In such circumstances, the NewLink Board may elect to, among other things, seek to out-license or partner with respect to our product candidates, divest all or a portion of our business, or take the steps necessary to liquidate all of our business and assets, and in either such case, the consideration that we receive may be less attractive than the consideration to be received by us pursuant to the Merger Agreement.

The exchange ratios are not adjustable based on the market price of NewLink's common stock so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.

Pursuant to the Merger Agreement, the applicable exchange ratios are included in Lumos' amended and restated certificate of incorporation, which does not include a price-based termination right and there will be no adjustment to the total number of shares of NewLink's common stock that Lumos stockholders and optionholders will be entitled to receive for changes in the market price of NewLink's common stock. Any changes in the market price of NewLink's common stock before the completion of the Merger will not affect the number of shares Lumos stockholders will be entitled to receive pursuant to the Merger Agreement. Therefore, if before the completion of the Merger the market price of NewLink's common stock increases from the market price on the date of the Merger Agreement, then Lumos stockholders could receive merger consideration with substantially more value for their shares of Lumos capital stock than the parties had negotiated for in the establishment of the exchange ratios.

Failure to complete the Merger may result in NewLink paying a termination fee or expenses to Lumos and could harm the common stock price of NewLink and future business and operations of NewLink.

If the Merger is not completed, we are subject to the following risks:

- if the Merger Agreement is terminated under certain circumstances, we may be required to pay a termination fee to Lumos of $2,000,000;
- the price of our stock may decline and remain volatile; and
- significant costs related to the Merger, such as legal and accounting fees which must be paid even if the Merger is not completed.

In addition, if the Merger Agreement is terminated and the NewLink Board determines to seek another business combination, there can be no assurance that we will be able to find a partner willing to provide equivalent or more attractive consideration than the consideration to be provided by Lumos.

If the conditions to the Merger are not met, the Merger may not occur.

Even if the Merger is approved by the NewLink stockholders, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or will be delayed, and we may lose some or all of the intended benefits of the Merger.

During the pendency of the Merger, NewLink may not be able to enter into a business combination with another party and will be subject to contractual limitations on certain actions because of restrictions in the Merger Agreement.

Covenants in the Merger Agreement impede the ability of NewLink to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the Merger. As a result, if the Merger is not completed, NewLink may be at a disadvantage to its competitors. In addition, while the Merger Agreement is in effect and subject to limited exceptions, each party is prohibited from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to the entering into certain extraordinary transactions with any third party, such as a sale of assets, an acquisition of NewLink's common stock, a tender offer for NewLink's common stock or a merger or other business combination outside the ordinary course of business. Any such transactions could be favorable to NewLink stockholders.

We may become involved in securities litigation or stockholder derivative litigation in connection with the Merger, and this could divert the attention of management and harm the combined company's business, and insurance coverage may not be sufficient to cover all related costs and damages.

Securities litigation or stockholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. We may become involved in this type of litigation in connection with the Merger, and the combined company may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect the business of NewLink and the combined company.

We are substantially dependent on our remaining employees to facilitate the consummation of the Merger.

We have substantially reduced our workforce since September 2019. Our ability to successfully complete the proposed merger depends in large part on our ability to retain our remaining personnel. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of any of these employees could potentially harm our ability to consummate the proposed merger, to run our day-to-day business operations, as well as to fulfill our reporting obligations as a public company.

Business Risks

Risks Related to Clinical Development and Commercialization of Our Product Candidates

If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them. We have not completed testing of any of our product candidates in controlled clinical trials.

The clinical development and regulatory approval process is expensive and time-consuming. The timing of any future product approval cannot be accurately predicted. If we fail to obtain regulatory approval for our current or future product candidates, we will be unable to market and sell them, and therefore we may never be profitable.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required varies depending on the product candidate, the condition being evaluated, the trial results and regulations applicable to any particular product candidate. Any inability to successfully complete preclinical and clinical development could result in additional costs to us.

Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Initial results may not be confirmed upon full analysis of the detailed results of a trial. Product candidates in later-stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

We will remain heavily dependent on the success of the clinical development of our drug product candidates, and if we fail to complete clinical trials, fail to demonstrate safety and efficacy in those clinical trials, fail to obtain regulatory approval or fail to commercialize any of our current or future drug product candidates successfully, our business, financial condition and results of operations would be harmed.

Our clinical development program currently encompasses a number of Phase 1 and 2 combination trials across multiple cancer indications. If we fail to complete any of these trials or fail to obtain regulatory approval, our ability to commercialize indoximod will be materially and adversely affected and our business, financial condition and results of operations would be harmed.

If we make changes to any of our product candidates, additional clinical trials may be required resulting in additional costs and delays.

We have an ongoing research program to investigate potential opportunities to improve the potency, efficacy and/or safety profile of some of our product candidates through modifications to their formulations or chemical compositions. These efforts may not be successful. If a new formulation or composition appears promising, we may decide to undertake clinical development of such formulation or composition even if an existing product candidate has shown acceptable safety and efficacy in clinical trials. The nature and extent of additional clinical trials that might be required for a new formulation or composition would depend on many factors. If we were to decide to pursue clinical development of a new formulation or composition, we would incur additional costs and the timeline for potential commercialization would be delayed. There can be no assurance that any new formulation or composition would prove to be safe or effective or superior to an existing product candidate. Any delay in commercialization of a new formulation or composition may adversely affect our competitive position.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle, including by allowing IND applications to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. Furthermore, our resource allocation decisions and our decisions about whether and how to develop or commercialize any particular product candidate may be based on evaluations of the scientific and commercial potential or target market for the product candidate that later prove to be materially inaccurate. If we enter into collaborations, licensing or other royalty arrangements to develop or commercialize a particular product candidate, we may relinquish valuable rights to that product candidate in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

We may face delays in completing our clinical trials, or we may not be able to complete them at all.

We have not completed all of the clinical trials necessary to support an application with the FDA for approval to market any of our product candidates. Our current and future clinical trials may be delayed or terminated as a result of many factors, including:

- we may experience delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- we may need to reformulate or change the dosing of our product candidates;
- our clinical trials may have slower than expected patient enrollment or lack of a sufficient number of patients that meet their enrollment criteria;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;
- we may experience difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our clinical trial protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials;
- our third-party contractors, including those manufacturing our product candidates or components of ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- we may experience governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines;
- enrollment in and conduct of our clinical trials may be adversely affected by the regulatory approval of competing agents in this class, competition with ongoing clinical trials or scheduling conflicts with participating clinicians; and
- we may experience delays in achieving clinical trial endpoints and completing data analysis for a trial.

In addition, we rely on academic institutions, physician practices and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other aspects of these clinical trials than if we conducted the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol or applicable regulations. We also may rely on clinical research organizations to perform our data management and analysis. They may not provide these services as required or in a timely or compliant manner.

Moreover, our development costs will increase if we are required to complete additional or larger clinical trials for our product candidates prior to FDA approval. If the delays or costs are significant, our financial results and ability to commercialize our product candidates will be adversely affected.

If we encounter difficulties enrolling patients in our clinical trials, our clinical trials could be delayed or otherwise adversely affected.

Clinical trials for our product candidates require us to identify and enroll a large number of patients with the disease under investigation, or healthy volunteers willing to participate in certain trials. We may not be able to enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a clinical trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- changes in the standard of care that make the trial as designed less attractive to clinicians and patients;
- availability of competing therapies and clinical trials, including announced clinical trials evaluating potentially competing IDO pathway inhibitors in clinical settings similar to our clinical trials;
- the results of clinical trials of other IDO pathway inhibitors;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Regulatory authorities may not approve our product candidates even if they meet safety and efficacy endpoints in clinical trials.

We have discussions with and obtain guidance from regulatory authorities regarding certain aspects of our clinical development activities. These discussions are not binding commitments on the part of regulatory authorities. Under certain circumstances, regulatory authorities may revise or retract previous guidance during the course of our clinical activities or after the completion of our clinical trials. A regulatory authority may also disqualify a clinical trial in whole or in part from consideration in support of approval of a potential product for commercial sale or otherwise deny approval of that product. Prior to regulatory approval, a regulatory authority may elect to obtain advice from outside experts regarding scientific issues and/or marketing applications under a regulatory authority review. In the United States, these outside experts are convened through the FDA's Advisory Committee process, which would report to the FDA and make recommendations that may differ from the views of the FDA. The FDA is not bound by the recommendations of an Advisory Committee, but it typically follows such recommendations. In addition, should an Advisory Committee be convened, it would be expected to lengthen the time for obtaining regulatory approval, if such approval is obtained at all.

The FDA and other foreign regulatory agencies can delay, limit or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- our manufacturing processes or facilities may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional work on our part.

Any delay in, or failure to receive or maintain, approval for any of our product candidates could prevent us from ever generating meaningful revenues or achieving profitability in future years.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may change requirements for approval even after a clinical trial design has been approved. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

Under the Merck Agreement, we have ongoing obligations related to the development of our Ebola vaccine product candidate, which may result in greater costs and a longer timeframe for regulatory approval than we estimate, yet we will receive limited revenues, if any, from any future sales of our Ebola vaccine product candidate.

Under the Merck Agreement, we have ongoing obligations related to the development of our Ebola vaccine product candidate, including obligations related to clinical trials, government contracting and licensing of the vaccine technology, which may cause us to incur costs or losses materially larger than we expect. However, because we have exclusively licensed the right to research, develop, manufacture and distribute our Ebola vaccine product candidate to Merck and we are only entitled to certain royalty and other payments under the Merck Agreement, we will receive limited revenues, if any, even if we or Merck are successful in developing and commercializing our Ebola vaccine product candidate.

The time and cost of product development and the timeframe for regulatory approval of any Ebola vaccine product candidate are uncertain and may be longer and more costly than we estimate. Our Ebola vaccine product candidate is a live virus based on vesicular stomatitis virus (VSV). There are no commercial vaccines based upon this virus, and unforeseen problems related to the use of our live virus vaccine may prevent or materially increase costs and delays of further development or approval of our Ebola vaccine product candidate. There may be unknown safety risks associated with the vaccine, and regulatory agencies such as the FDA may require us to conduct extensive safety testing prior to approval to demonstrate a low-risk of rare and severe adverse events caused by the vaccine.

Public perception of vaccine safety issues, including adoption of novel vaccines based upon VSV, may adversely influence willingness of subjects to participate in clinical trials, or if approved, of physicians to prescribe, and of patients to receive, novel vaccines. For example, our Ebola vaccine product candidate is currently being developed for the prevention of, and may later be developed for the treatment of patients infected with, Ebola, and public aversion to vaccines for Ebola or vaccines in general may adversely influence later-stage clinical trials of this product candidate or, if approved, its commercial success.

Even if approved, a number of factors may adversely affect commercial sales. Lack of familiarity with the viral vaccine and potential adverse events associated with vaccination may adversely affect physician and patient perception and uptake of our potential product. Furthermore, there are no assurances that the vaccine will be approved for inclusion in government stockpile programs, which may be material to the commercial success of the product candidate, either in the United States or abroad. If our Ebola vaccine product candidate eventually is approved and sold commercially, we will receive limited revenues under the Merck Agreement. Finally, in certain cases, our obligations to pay royalties to PHAC may exceed the royalties we receive from Merck.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's Good Clinical Practice (GCP) requirements, or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and Institutional Review Boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under current Good Manufacturing Practice (cGMP) requirements and may require large numbers of test subjects. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- the product candidate may have unforeseen adverse side effects;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- failure to demonstrate a benefit from using a drug;
- the quality or stability of the product candidate may fall below acceptable standards; or
- insufficient quantities of the product candidate to complete the trials.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors indoximod, NLG802, NLG207, NLG919, and other product candidates could take significantly longer to gain regulatory approval than we expect or we may never gain approval for additional indications, which could reduce our revenue by delaying or terminating their commercialization.

Some of our product candidates have been studied, or in the future may be studied, in clinical trials co-sponsored by organizations or agencies other than us, or in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.

We have in the past and currently supply indoximod in support of Phase 2 investigator-initiated clinical trials, and we provided clinical supply of dorgenmeltucel-L in support of a Phase 2 investigator-initiated clinical trial. Our Ebola vaccine product candidate was studied in clinical trials in West Africa. We may continue to supply and otherwise support similar trials in the future. However, because we are not the sponsors of these trials, we do not control the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment, and, as a result, are subject to risks associated with the way these types of trials are conducted, in particular should any problems arise. These risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data.

If we cannot demonstrate the safety of our product candidates in preclinical and/or other non-clinical studies, we will not be able to initiate or continue clinical trials or obtain approval for our product candidates.

In order to move a product candidate not yet being tested in humans into a clinical trial, we must first demonstrate in preclinical testing that the product candidate is safe. Furthermore, in order to obtain approval, we must also demonstrate safety in various preclinical and non-clinical tests. We may not have conducted or may not conduct in the future the types of preclinical and other non-clinical testing ultimately required by regulatory authorities, or future preclinical tests may indicate that our product candidates are not safe for use in humans. Preclinical testing is expensive, can take many years and can have an uncertain outcome. In addition, success in initial preclinical testing does not ensure that later preclinical testing will be successful. We may experience numerous unforeseen events during, or as a result of, the preclinical testing process, which could delay or prevent our ability to develop or commercialize our product candidates, including:

- our preclinical testing may produce inconclusive or negative safety results, which may require us to conduct additional preclinical testing or to abandon product candidates that we believed to be promising;
- our product candidates may have unfavorable pharmacology, toxicology or carcinogenicity;
- our product candidates may cause undesirable side effects; and
- the FDA or other regulatory authorities may determine that additional safety testing is required.

Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition and results of operations.

Even if ultimately approved, indoximod, NLG802, NLG207, NLG919, our Ebola vaccine product candidate or any other potential product we or our collaborators may commercialize and market may be later withdrawn from the market or subject to promotional limitations.

We or our collaborators may not be able to obtain the labeling claims necessary or desirable for the promotion of any potential future products. We or our collaborators may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory, the FDA or a comparable agency in a foreign country may withdraw marketing authorization or may condition continued marketing on commitments from us or our collaborators that may be expensive and/or time-consuming to fulfill. In addition, if we or others identify adverse side effects after any of our potential products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our potential products, additional clinical trials, changes in labeling of our potential products and/or additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of our potential products.

We will need to develop or acquire additional capabilities in order to commercialize any product candidates that obtain FDA approval, and we may encounter unexpected costs or difficulties in doing so.

We will need to acquire additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. Currently, we have limited experience in preparing applications for marketing approval, commercial-scale manufacturing, managing large-scale information technology systems or managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources.

To do this effectively, we must:

- train, manage and motivate a growing employee base;
- accurately forecast demand for our products; and
- expand existing operational, financial and management information systems.

We will need to increase our manufacturing capacity, which may include negotiating and entering into additional third-party agreements to meet our commercial manufacturing requirements.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate significant product revenue.

We do not have a sales organization and have no experience in the sales and distribution of pharmaceutical products. There are risks involved with establishing our own sales capabilities and increasing our marketing

capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us could potentially be lower than if we market and sell these products ourselves.

We entered into the Merck Agreement in November 2014 for the research, development, manufacture and distribution of our Ebola vaccine product candidate. Even if our Ebola vaccine product candidate is approved by regulators for marketing and sale, Merck may be unsuccessful in its efforts to commercialize our Ebola vaccine product candidate, respectively, or may devote fewer resources to such efforts than we would consider optimal.

We may establish our own specialty sales force and/or engage other biopharmaceutical or other healthcare companies with established sales, marketing and distribution capabilities to sell, market and distribute any future products. We may not be able to establish a specialty sales force or establish sales, marketing or distribution relationships on acceptable terms. Factors that may inhibit our efforts to commercialize any future products without strategic collaborators or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to an adequate number of physicians to educate them about the attributes of any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Because the establishment of sales, marketing and distribution capabilities depends on the progress toward commercialization of our product candidates, and because of the numerous risks and uncertainties involved with establishing those capabilities, we are unable to predict when, if ever, we will establish our own sales, marketing and distribution capabilities. If we are not able to collaborate with third parties and are unsuccessful in recruiting sales, marketing and distribution personnel or in building the necessary infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

Failure to attract and retain key personnel could impede our ability to develop our products and to obtain new collaborations or other sources of funding.

Because of the specialized scientific nature of our business, our success is highly dependent upon our ability to attract and retain qualified scientific and technical personnel, consultants and advisors. We are highly dependent on the principal members of our scientific and management staff. Effective August 3, 2019 Charles J. Link, Jr., our founder and former Chief Executive Officer, Chief Scientific Officer and Chairman of the Board, retired from his posts as Chairman, Chief Executive Officer and Chief Scientific Officer and as a member of the Board of Directors of the Company. Effective September 27, 2019, Dr. Nicholas Vahanian retired from his posts as President and a member of the Board. These changes, or the long-term loss of services of any other key executives, might significantly delay or prevent the achievement of our research, development, and business objectives. We do not maintain key-man life insurance with respect to any of our employees, nor do we intend to secure such insurance.

We will need to recruit additional personnel in order to achieve our operating goals. In order to pursue product development and marketing and sales activities, if any, we will need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales. We also rely on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on acceptable terms, if at all. Additionally, our most significant facility is located in Iowa, which may make attracting and retaining qualified scientific and technical personnel from outside of Iowa difficult. The failure to attract and retain qualified personnel, consultants and advisors could have a material adverse effect on our business, financial condition and results of operations.

Our workforce reduction may cause undesirable consequences and our results of operations may be harmed.

On September 30, 2019, we commenced a restructuring plan in the context of the anticipated merger. Under the restructuring plan, we reduced our workforce by 28 employees (approximately 60%), including several members of management. This workforce reduction may yield unintended consequences, such as attrition beyond our intended reduction in workforce and reduced employee morale, which may cause our employees who were not affected by the reduction in workforce to seek alternate employment. Additional attrition could impede our ability to meet our operational goals. In addition, as a result of the reductions in our workforce, we may face an increased risk of employment litigation. Furthermore, employees whose positions were eliminated or those who determine to seek alternate employment may seek employment with our competitors. We cannot assure you that we will be able to realize the cost savings and other anticipated benefits from our previous or any future reduction plans.

Risks Related to Manufacturing Activities

We rely on third-party manufacturers to produce our preclinical and clinical product candidate supplies and we intend to rely on third parties to produce commercial supplies of any product candidates that may be approved in the future. Any failure by a third-party manufacturer to produce supplies for us may delay or impair our ability to complete our clinical trials or commercialize our product candidates.

We do not possess all of the capabilities to fully commercialize any of our product candidates on our own. If we are unable to arrange for third-party manufacturing sources or to do so on commercially reasonable terms, we may not be able to complete development of such product candidates or market them. In addition, we currently rely on our partner Merck for the supply of our Ebola vaccine product candidate and other third party manufacturers for our supply of indoximod, NLG802, NLG207, and NLG919 for preclinical and clinical studies. Problems with any of our facilities or processes, or our contract manufacturers' facilities or processes, could prevent or delay the production of adequate supplies of indoximod, NLG802, NLG207, NLG919, our Ebola vaccine product candidate or other finished products.

Any prolonged delay or interruption in the operations of our current or future contract manufacturers' facilities could result in cancellation of shipments, loss of components in the process of being manufactured or a shortfall in the availability of a product. A number of factors could cause interruptions, including the inability of a supplier to provide raw materials, equipment malfunctions or failures, damage to a facility due to natural disasters, changes in international or U.S. regulatory requirements or standards that require modifications to our manufacturing processes, action by regulatory authorities or by us that results in the halting or slowdown of production of components or finished product due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified production capacity and sufficiently trained or qualified personnel may not be available on a timely or cost-effective basis or at all. Difficulties or delays in our contract manufacturers' production of product candidates could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue and market share if we are unable to meet market demand for any products that are approved for sale on a timely basis.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, failure of the third party to accept orders for supply of drug substance or drug product and the possibility of termination or nonrenewal of the agreement by the third-party based on its own business priorities and at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes as needed, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates that may have been granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture our product candidates. Such suppliers may not sell this capital equipment or these raw materials to our manufacturers at the times we need them or on commercially reasonable terms. We do

not have any control over the process or timing of the acquisition of this capital equipment or these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Because of the complex nature of many of our early-stage compounds and product candidates, our manufacturers may not be able to manufacture such compounds and product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize related products. If we successfully commercialize any of our product candidates, we may be required to establish or access large-scale commercial manufacturing capabilities. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. To meet our projected needs for commercial manufacturing in the event that one or more of our product candidates gains marketing approval, third parties with whom we currently work will need to increase their scale of production or we will need to secure alternate suppliers.

Furthermore, we do not currently have experience with the management of relationships related to commercial-scale contract manufacturing, and we may incur substantial costs to develop the capability to negotiate and enter into relationships with third-party contract manufacturers.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our products.

All entities involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our Company, our existing contract manufacturers and those we may engage in the future, and Merck in its capacity as our licensee, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP regulations. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of any of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. In addition, to the extent that we rely on foreign contract manufacturers, as we do currently for our Ebola vaccine product candidate, we are or will be subject to additional risks including the need to comply with export and import regulations.

If our current or future contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

Our facility is located in areas where floods and tornados are known to occur, and the occurrence of a flood, tornado or other catastrophic disaster could damage our facilities and equipment, which could cause us to curtail or cease operations.

Our primary facility is located in Ames, Iowa, which is susceptible to floods and tornados, and our facility is therefore vulnerable to damage or disruption from floods and tornados. We are also vulnerable to damage from other types of disasters, such as power loss, fire and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We currently carry business insurance (real, personal and business income) of approximately $14.4 million in the aggregate, but this policy does not cover disasters such as floods and earthquakes.

We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our information technology infrastructure, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber-attacks. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent the adverse effect of such events. Significant disruptions of our information technology systems or breaches of data security could adversely affect our business.

Risks Related to Regulation of Our Industry

The industry within which we operate and our business are subject to extensive regulation, which is costly and time-consuming and which may subject us to unanticipated delays.

The research, development, testing, manufacturing, labeling, packaging, marketing, distribution, promotion and advertising of biologic and pharmaceutical products such as our product candidates are subject to extensive regulation by governmental regulatory authorities in the United States and other countries. The drug development and approval process is generally lengthy, expensive and subject to unanticipated delays. Data obtained from preclinical and clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of development and regulatory review of each submitted application for approval. To obtain approval for a product candidate, we must demonstrate to the satisfaction of the regulatory authorities that the product candidate is safe and effective in the case of a small-molecule pharmaceutical product, or is safe, pure and potent in the case of a biologic, which typically takes several years or more depending upon the type, complexity and novelty of the product and requires the expenditure of substantial resources.

There can be no assurance that we will not encounter problems in clinical trials that would cause us or the regulatory authorities to delay or suspend clinical trials. Any such delay or suspension could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that we will not encounter problems in clinical trials that would cause us or the regulatory authorities to delay or suspend clinical trials. Any such delay or suspension could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that clinical trials for any of our product candidates currently under development will be completed successfully or within any specified time period, if at all. Further, there can also be no assurance that such testing will show any product to be safe, pure, potent or effective. We cannot predict when, if ever, we might submit for regulatory review our product candidates currently under development. In addition, regardless of how much time and resources we devote to the development of a product candidate, there can be no assurance that regulatory approval will be obtained for that product candidate.

Even if such regulatory approval is obtained, we, our products and any contract manufacturers or commercial collaborators of ours will be subject to continual regulatory review in both the United States and other countries. Later discovery of previously unknown problems with regard to a product, distributor or manufacturer may result in restrictions, including withdrawal of the product from the market and/or disqualification or decertification of the

distributor or manufacturer. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- warning letters;
- civil or criminal penalties;
- injunctions;
- suspension of or withdrawal of regulatory approval;
- total or partial suspension of any ongoing clinical trials or of production;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of new biologic and pharmaceutical products through lengthy and detailed preclinical and clinical testing procedures, sampling activities and other costly and time-consuming compliance procedures. Clinical trials are vigorously regulated and must meet requirements for FDA review and oversight and requirements under GCP guidelines. A new drug may not be marketed in the United States until the FDA has approved it. There can be no assurance that we will not encounter delays or rejections or that the FDA will not make policy changes during the period of product development and FDA regulatory review of each submitted BLA and new drug application (NDA). A delay in obtaining, or failure to obtain, such approvals would have a material adverse effect on our business, financial condition and results of operations. Even if regulatory approval were obtained, it would be limited as to the indicated uses for which the product may be promoted or marketed. A marketed product, its manufacturer and the facilities in which it is manufactured are subject to continual review and periodic inspections. If marketing approval is granted, we would be required to comply with FDA requirements for manufacturing, labeling, advertising, record-keeping and reporting of adverse experiences and other information. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label, although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications. Companies may also share truthful and not misleading information that is otherwise consistent with the labeling. In addition, we would be required to continue to comply with federal and state anti-kickback and other healthcare fraud and abuse laws that pertain to the marketing of pharmaceuticals, among other things. Failure to comply with regulatory requirements and other factors could subject us to regulatory or judicial enforcement actions, including product recalls or seizures, injunctions, withdrawal of the product from the market, civil penalties, criminal prosecution, refusals to approve new products and withdrawals of existing approvals, as well as enhanced product liability exposure, any of which could have a material adverse effect on our business, financial condition and results of operations. Sales of our products outside the United States will be subject to foreign regulatory requirements governing clinical trials, marketing approval, manufacturing and pricing. Noncompliance with these requirements could result in enforcement actions or penalties or could delay the introduction of our products in certain countries.

The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement outside the United States vary greatly from country to country. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Foreign regulatory authorities could also require additional testing. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our products and may have a material adverse effect on our results of operations and financial condition.

We are also subject to laws generally applicable to businesses including, but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful

workplace discrimination and whistleblowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistleblowing claim, even if without merit, could result in costly litigation or regulatory action or otherwise harm our business, results of operations, financial condition, cash flow and future prospects.

The availability of coverage and amount of reimbursement for our product candidates, if approved, and the manner in which government and private payers may reimburse for our potential products, are uncertain.

In both the United States and foreign markets, sales of our proposed products will depend in part on the availability of coverage and reimbursement from third-party payers such as government health administration authorities, private health insurers and other organizations. In addition, the process for determining whether a third party payor will provide coverage for a pharmaceutical typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payer will pay for the product once coverage is approved. Third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. There can be no assurance that our proposed products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Our future levels of revenues and profitability may be affected by the continuing efforts of governmental and third-party payers to contain or reduce the costs of healthcare. We cannot predict the effect that private sector or governmental health care reforms may have on our business, and there can be no assurance that any such reforms will not have a material adverse effect on our business, financial condition and results of operations. Legislation and regulations affecting the pricing of pharmaceuticals may change before any of our proposed products are approved for marketing. Adoption of such legislation could further limit reimbursement for medical products and services. As a result, we may elect not to market future products in certain markets.

Moreover, while we are in clinical trials, we will not be reimbursed for any of our materials used during the clinical trials, however, certain services rendered to clinical trial participants may be reimbursable by third-party payors for standard of care treatment if not otherwise reimbursed under the applicable clinical trial study budget.

The biopharmaceutical industry is subject to significant regulation and oversight in the United States, in addition to approval of products for sale and marketing; our failure to comply with these laws could harm our results of operations and financial condition.

In addition to FDA restrictions on marketing of biopharmaceutical products, our operations may be directly, or indirectly through our relationships with healthcare providers, customers and third-party payers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute. These laws may impact, among other things, our proposed sales, and education programs, and these laws have been applied to restrict certain marketing practices in the biopharmaceutical industry. In addition, we may be subject to patient privacy regulation by both the U.S. federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, among others, the following:

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.
- The federal civil False Claims Act prohibits any person or entity from knowingly presenting, or causing to be presented, to the federal government a claim for payment or approval that is false or fraudulent or from

knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Several pharmaceutical and other health-care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of off-label promotion. Private parties may initiate qui tam whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit.

- The federal Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA), imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their implementing regulations imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization on covered entities, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information.
- The federal Food, Drug and Cosmetic Act (FDCA) prohibits, among other things, the adulteration or misbranding of drugs and medical devices.
- The federal Physician Payments Sunshine Act, and its implementing regulations require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services (CMS), information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members.
- Analogous state laws and regulations include: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information and that require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. It is possible that some of our business activities could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business, financial condition and results of operations.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken

several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that required that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order included a budget neutrality provision that required the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations that can be repealed to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the United States Office of Management and Budget on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. Further, on February 24, 2017, President Trump issued an Executive Order requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification. It is difficult to predict how these requirements will continue to be enforced, the extent to which they will continue to impact the FDA's ability to exercise its regulatory authority, and the negative impact they may have on our business.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The U.S. and some foreign jurisdictions are considering or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, in the United States, the pharmaceutical industry has been affected by the passage of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the ACA), which, among other things, imposed new fees on entities that manufacture or import certain branded prescription drugs and expanded pharmaceutical manufacturer obligations to provide discounts and rebates to certain government programs. There have been judicial and congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (the BBA) among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Although the Texas U.S. District Court Judge, as well as the presidential administration and CMS have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, there has been particular and increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices in recent years, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. There have been several recent U.S. Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. While some of the existing measures and other proposed measures will require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. This final rule codified CMS's policy change that was effective January 1, 2019. Any of these initiatives could harm our ability to generate revenues.

In the future, there will likely continue to be proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of drug products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Individual states are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payers or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which pharmaceutical products and suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last 10 years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (the Right to Try Act) was signed into law. The law, among other things, provides a federal framework for certain patients to access certain IND products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislative or administrative action, either in the United States or abroad.

We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

Our research and development involves the controlled use of hazardous materials, chemicals, various active microorganisms and volatile organic compounds, and we may incur significant costs as a result of the need to comply with numerous laws and regulations. We are subject to laws and regulations enforced by the FDA, the Drug Enforcement Agency, foreign health authorities and other regulatory requirements, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Food, Drug and Cosmetic Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of our products, materials used to develop and manufacture our product candidates, and resulting waste products. Although we believe that our safety procedures for handling and disposing of such materials, and for killing any unused microorganisms before disposing of them, comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Failure to comply with existing or future data protection laws and regulations related to privacy or data security could lead to government enforcement actions (which could include civil or criminal fines or penalties), private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

Regulation of data processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. We and our partners may be subject to current, new, or modified federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our partners to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our partners' ability to process or use data in order to support the provision of our products or services, or affect our or our partners' ability to offer our products and services in certain locations.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to civil and/or criminal penalties including if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including, without limitation, the European Union Directive 95/46/EC (the Directive), and the European Union's General Data Protection Regulation (the GDPR) that took effect in May 2018, and member state data protection legislation, may also apply to health-related and other personal information obtained outside of the United States. These laws impose strict obligations on the ability to process health-related and other personal information of data subjects in the European Union, including in relation to use, collection, analysis and transfer of such personal information. These laws include several requirements relating to the consent of the individuals to whom the personal data relates, limitations on data processing, establishing a legal basis for processing, notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, the security and confidentiality of the personal data and various rights that data subjects may exercise.

The Directive and the GDPR prohibits, without an appropriate legal basis, the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions.

Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with European Union data protection laws remains. For example, ongoing legal challenges in Europe to the mechanisms allowing companies to transfer personal data from the EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers, such as the European Union-U.S. and Swiss-U.S. Privacy Shield framework. Additionally, other countries have passed or are considering passing laws requiring local data residency.

Under the GDPR, regulators may impose substantial fines and penalties for non-compliance. Companies that violate the GDPR can face fines of up to the greater of 20 million Euros or 4% of their worldwide annual turnover (revenue). The GDPR has increased our responsibility and liability in relation to personal data that we process, requiring us to put in place additional mechanisms to ensure compliance with the GDPR and other EU and international data protection rules.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations related to security or privacy, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Compliance with data protection laws may be time-consuming, require additional resources and could result in increased expenses, reduce overall demand for our products and services and make it more difficult to meet expectations of our commitments to customers or partners.

Any of these matters could materially adversely affect our business, financial condition, or operational results.

Financial Risks

We have a history of net losses. We incurred a net loss for the years ended December 31, 2016, 2017 and 2018 and expect to continue to incur net losses for the foreseeable future, and we may never achieve or maintain profitability in the future.

We were profitable in the year ended December 31, 2014, primarily as a result of upfront payments under the Genentech Agreement and the Merck Agreement. We are not entitled to receive any additional upfront payments under these licensing or collaboration agreements. We do not expect any milestone or royalty payments under these or other agreements, if any, to be sufficient to make us profitable in future years. We incurred a loss of $34.7 million for the nine months ended September 30, 2019 and we do not expect to be profitable for the foreseeable future. We anticipate that we will continue to incur operating losses over the next several years as we continue our clinical development programs.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities, government grants, economic development loans and capital lease and equipment financing. The size of our future net losses will depend, in part, on the rate of growth or contraction of our expenses and the level and rate of growth, if any, of our revenues. Our ability to achieve profitability in future years is dependent on our ability, alone or with others, to complete the development of our products successfully, obtain the required regulatory approvals, manufacture and market our proposed products successfully or have such products manufactured and marketed by others and gain market acceptance for such products. There can be no assurance as to whether or when we will achieve profitability.

We may require substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

Development of our product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution capabilities, either internally or through collaborations with third parties. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings (including FDA review of any BLA or NDA we file);
- payments required with respect to development milestones we achieve under our in-licensing agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the costs associated with commercializing our product candidates, if they receive regulatory approval;
- the cost of manufacturing our product candidates and any products we commercialize;
- the cost and timing of developing our ability to establish sales and marketing capabilities;
- the potential requirement to repay our outstanding government provided loans;
- competing technological efforts and market developments;
- changes in our existing research relationships;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing and receipt of revenues from existing or future products, if any; and
- payments received under any future strategic collaborations.

We anticipate that we will continue to generate significant losses in the future to the extent we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates. We believe that our existing cash and cash equivalents will allow us to fund our operating plan in the near and medium term. However, our operating plan may change as a result of factors currently unknown to us.

There can be no assurance that our revenue and expense forecasts will prove to be accurate, and any change in the foregoing assumptions could require us to obtain additional financing earlier than anticipated. There is a risk of delay or failure at any stage of developing a product candidate, and the time required and costs involved in successfully accomplishing our objectives cannot be accurately predicted. Actual drug research and development costs could substantially exceed budgeted amounts, which could force us to delay, reduce the scope of or eliminate one or more of our research or development programs.

We are party to license agreements with various parties pursuant to which we have obtained licenses to certain patents, patent applications and other intellectual property related to our product candidates and product development efforts. We are obligated to make aggregate payments ranging from approximately $250,000 to $2.8 million under our license agreements (and in some cases, for each product candidate in such license) upon achievement of development and regulatory approval milestones specified in the applicable license. The timing of our achievement of these events and corresponding milestone payments to our licensors is subject to factors relating to the clinical and regulatory development and commercialization of our product candidates, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization or marketing efforts or seek funds to meet these obligations on terms unfavorable to us.

We may never be able to generate a sufficient amount of product revenue to cover our expenses. Until we do, we expect to seek additional funding through public or private equity or debt financings, collaborative relationships, capital lease transactions or other available financing transactions. However, there can be no assurance that additional financing will be available on acceptable terms, if at all, and such financings could be dilutive to existing stockholders. Moreover, in the event that additional funds are obtained through arrangements with collaborators, such arrangements may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs. Our failure to obtain adequate financing when needed and on acceptable terms would have a material adverse effect on our business, financial condition and results of operations.

Even though we have received governmental support in the past, we may not continue to receive support at the same level or at all.

We have received significant financial assistance, primarily in the form of forgivable loans, from state and local governments. We have also received significant financial assistance, primarily in the form of grants and contracts, from federal agencies to support our infectious disease research. There can be no assurance that we will continue to receive the same level of assistance from these or other government agencies, if at all.

Through our subsidiary, BPS, we have received funding from multiple government agencies for our Ebola vaccine product candidate development efforts. There is no guarantee that we will receive sufficient, or any, future grant funding to meet our obligations related to our Ebola vaccine development or that we or Merck will succeed in developing an Ebola vaccine. The termination of a United States government grant, contract or relationship as a result of our failure to satisfy any of our obligations under the grants or contracts would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, there can be no assurance that we will secure comparable contracts with, or grants from, the United States government in the future.

Changes in our effective income tax rate could adversely affect our results of operations in the future.

For the nine months ended September 30, 2019 we have no income tax benefit or expense. Our effective income tax rate, as well as our relative domestic and international tax liabilities, will depend in part on the allocation of any future income among different jurisdictions. In addition, various factors may have favorable or unfavorable effects on our effective income tax rate in individual jurisdictions or in the aggregate. These factors include whether tax authorities agree with our interpretations of existing tax laws, any required accounting for stock options and other share-based compensation, changes in tax laws and rates (including the recently enacted U.S. federal income tax law changes), our future levels of research and development spending, changes in accounting standards, changes in the mix of any future earnings in the various tax jurisdictions in which we may operate, the outcome of any examinations by the U.S. Internal Revenue Service or other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings. The effect on our income tax liabilities resulting from the above-mentioned factors or other factors could have a material adverse effect on our results of operations.

The comprehensive tax reform bill of 2017 could adversely affect our business and financial condition.

On December 22, 2017 the Tax Act was signed into law. The Tax Act significantly revised the Internal Revenue Code of 1986, as amended (the Code) and included, among other things, significant changes to corporate taxation, including a reduction of the corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income for net operating losses arising in taxable years beginning after December 31, 2017 and elimination of net operating loss carrybacks for net operating losses arising in taxable years beginning after December 31, 2017, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act did not have a material impact on our business. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to the Tax Act and the potential tax consequences of investing in or holding our common stock.

Risks Related to Competition

We compete in an industry characterized by extensive research and development efforts and rapid technological progress. New discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive.

New developments occur and are expected to continue to occur at a rapid pace, and there can be no assurance that discoveries or commercial developments by our competitors will not render some or all of our potential products obsolete or non-competitive, which would have a material adverse effect on our business, financial condition and results of operations.

We expect to compete with fully integrated and well-established pharmaceutical and biotechnology companies in the near and long term. Most of these companies have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. Such companies may succeed in discovering and developing pharmaceutical products more rapidly than we do or pharmaceutical products that are safer, more effective or less costly than any that we may develop. Such companies also may be more successful than we are in production and marketing. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations also conduct clinical trials, seek patent protection and establish collaborative arrangements for the development of oncology products.

We may face competition based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, reimbursement coverage, price and patent position. There can be no assurance that our competitors will not develop safer and more effective products, commercialize products earlier than we do, or obtain patent protection or intellectual property rights that limit our ability to commercialize our products.

There can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide us with proprietary protection or a competitive advantage.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Many of the products that we are attempting to develop and commercialize will be competing with existing therapies. In addition, a number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies both in the United States and abroad. Our competitors may utilize discovery technologies and techniques or collaborate with third parties in order to develop products more rapidly or successfully than we or our collaborators are able to do. Many of our competitors, particularly large pharmaceutical companies, have substantially greater financial, technical and human resources than we do. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors.

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies, firms specialized in the development and production of vaccines, checkpoint inhibitors, and other immunotherapies, and major universities and research institutions. Many companies have entered into the field of immuno-oncology and are developing or commercializing products in areas that we have targeted for product development. Some of these products use therapeutic approaches that may compete directly with our product candidates. Most of our competitors possess substantially greater financial, technical and human resources than we possess. In addition, many of our competitors have significantly greater experience than we have in conducting preclinical and nonclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of drugs and manufacturing facilities. Accordingly, our competitors may succeed in obtaining regulatory approval for drugs more rapidly than we do. We expect to face growing competition for enrollment of patients in our clinical trials, which could delay or adversely affect our ability to complete such trials. We may also be adversely affected by the clinical trial results of our competitors. For example, if a competitor announces inconclusive or negative clinical trial results with respect to an IDO pathway inhibitor, expectations about IDO pathway inhibitors may be generally

impacted and we may experience difficulty in enrolling patients in our indoximod trials. If we obtain regulatory approval and launch commercial sales of our product candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

We also face competition from pharmaceutical and biotechnology companies, academic institutions, government agencies and private research organizations in recruiting and retaining highly qualified scientific personnel and consultants and in the development and acquisition of technologies. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, thereby preventing us from obtaining technology on commercially reasonable terms, if at all. We will also compete for the services of third parties that may have already developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies to target the diseases on which we have focused both inside and outside of the United States.

Our competitive position will also depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often lengthy period between technological conception and commercial sales. We will require substantial capital resources to complete development of some or all of our products, obtain the necessary regulatory approvals and successfully manufacture and market our products. In order to secure capital resources, we may elect to sell additional capital stock, which would dilute the holdings of existing stockholders. We may also attempt to obtain funds through research grants and agreements with commercial collaborators. However, these types of financings are uncertain because they are at the discretion of the organizations and companies that control the funds. Accordingly, we may not receive any additional funds from grants or collaborations.

Research and discoveries by others may result in breakthroughs that render indoximod, NLG802, NLG207, and NLG919 product candidates, or our other potential products obsolete even before they begin to generate any revenue. If the FDA approves the commercial sale of any of our product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited or no experience. We expect that competition among products approved for sale will be based, among other things, on product efficacy, price, safety, reliability, availability, patent protection, and sales, marketing and distribution capabilities. Our profitability and financial position will suffer if our products receive regulatory approval but cannot compete effectively in the marketplace.

Our future products, if any, may not be accepted in the marketplace and therefore, we may not be able to generate significant revenue, or any revenue.

Even if our potential products are approved for sale, physicians and the medical community may not ultimately use them or may use them only in applications more restricted than we expect. Our future products, if successfully developed, will compete with a number of traditional immuno-oncology products manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products will also compete with new products currently under development by such companies and others. Physicians will prescribe a product only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is beneficial as compared to other products currently in use. Many other factors influence the adoption of new products, including marketing and distribution restrictions, course of treatment, adverse publicity, product pricing, the views of thought leaders in the medical community and coverage and adequate reimbursement by government and private third-party payers.

Risks Related to Our Arrangements with Third Parties

We rely on third parties to conduct our preclinical studies and our clinical trials. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for our product candidates, or we may be delayed in doing so.

We do not have the ability to conduct preclinical studies or clinical trials independently for our product candidates. We must rely on third parties, such as contract research organizations, medical institutions, academic institutions, clinical investigators and contract laboratories, as well as our strategic collaborators and the third parties that they may use, to conduct our preclinical studies and clinical trials. Other than to the extent that Merck is responsible for clinical trials of our Ebola vaccine product candidate, we are responsible for confirming that our studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with GLP for conducting and recording the results of our preclinical studies and with GCP for conducting, monitoring, recording

and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with GCP, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be more costly than expected or budgeted, be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or to commercialize the product candidate being tested in such trials, or may be delayed in doing so.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

We are also dependent on Merck for the development of the product candidates that are the subject of the Merck Agreement. If the company does not succeed in advancing the product candidate to final approval, or decides to discontinue its collaboration with us, such failure or decision, could materially harm our business.

If we fail to enter into any needed collaboration agreements for our product candidates, or if we enter into collaborations that are ultimately unsuccessful, we may be unable to commercialize any potential product effectively or at all.

To successfully commercialize any potential product, we will need substantial financial resources as well as expertise and physical resources and systems. We may elect to develop some or all of these physical resources and systems and expertise ourselves or we may seek to collaborate with another company that can provide some or all of such physical resources and systems as well as financial resources and expertise, as we did in the case of the Genentech Agreement and the Merck Agreement. Such collaborations are complex, and any potential discussions may not result in a definitive agreement for many reasons. For example, whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the potential market for the subject product candidates, the costs and complexities of manufacturing and delivering the potential product to patients, the potential of competing products, the existence of uncertainty with respect to ownership or the coverage of our technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. If we were to determine that a collaboration for a potential product is necessary or beneficial and were unable to enter into such a collaboration on acceptable terms, we might elect to delay or scale back the commercialization of the potential product in order to preserve our financial resources or to allow us adequate time to develop the required physical resources and systems and expertise ourselves.

If we enter into a collaboration agreement we consider acceptable, including the Merck Agreement to develop and commercialize our Ebola vaccine product candidate, the collaboration may not proceed as quickly, smoothly or successfully as we plan. The risks in a collaboration agreement include the following:

- the collaborator may not apply the expected financial resources, efforts or required expertise in developing the physical resources and systems necessary to successfully commercialize the subject potential product;
- the collaborator may not invest in the development of a sales and marketing force and the related infrastructure at levels that ensure that sales of the potential product reach their full potential;
- disputes may arise between us and a collaborator that delay the commercialization or adversely affect its sales or profitability of the potential product; or
- the collaborator may independently develop, or develop with third parties, products that could compete with the potential product.

Under the Merck Agreement and any other collaboration for our product candidates, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates, and such disputes may be

difficult and costly to resolve or may not be resolved. In addition, a collaborator for the potential product may have the right to terminate the collaboration at its discretion, or to discontinue development of a particular product candidate. For example, in June 2017, Genentech gave notice that it was terminating the Genentech Agreement with respect to NLG919 and gave notice in May 2018 that the remainder of the Agreement would terminate no later than November 6, 2018. Further, Merck has the right to terminate the Merck Agreement for any reason after a specified advance notice period. Any termination may require us to seek a new collaborator, which we may not be able to do on a timely basis, if at all, or may require us to delay or scale back the development or commercialization efforts. The occurrence of any of these events could adversely affect the development or commercialization of the potential product and materially harm our business and stock price by delaying the sale of any product that may be approved by the FDA in the future, by slowing the growth of such sales, by reducing the profitability of the product and/or by adversely affecting the reputation of the product.

We may explore strategic collaborations that may never materialize or may fail.

We may, in the future, periodically explore a variety of possible strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in the process of seeking appropriate strategic collaborators, and such collaborations can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

We are required under the Merck Agreement, and we may be required under other collaborations, to relinquish important rights to and control over the development of our product candidates to our collaborators or otherwise be subject to unfavorable terms.

Our collaborations, including any future strategic collaborations we enter into, could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- other than under the Merck Agreement, we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

- business combinations or significant changes in a strategic collaborator's business strategy may also adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Risks Related to Protecting Our Intellectual Property

If we are unable to protect our proprietary rights or to defend against infringement claims, we may not be able to compete effectively or operate profitably.

Our success will depend, in part, on our ability to obtain patents, operate without infringing the proprietary rights of others and maintain trade secrets, both in the United States and other countries. Patent matters in the biotechnology and pharmaceutical industries can be highly uncertain and involve complex legal and factual questions. Accordingly, the validity, breadth, and enforceability of our patents and the existence of potentially blocking patent rights of others cannot be predicted, either in the United States or in other countries.

There can be no assurance that we will discover or develop patentable products or processes, or that patents will issue from any of the currently pending patent applications or that claims granted on issued patents will be sufficient to protect our technology or adequately cover the products we may actually sell. Potential competitors or other researchers in the field may have filed patent applications, been issued patents, published articles or otherwise created prior art that could restrict or block our efforts to obtain additional patents. There also can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated, rendered unenforceable or circumvented or that the rights granted thereunder will provide us with proprietary protection or competitive advantages. Our patent rights also depend on our compliance with technology and patent licenses upon which our patent rights are based and upon the validity of assignments of patent rights from consultants and other inventors that were, or are, not employed by us.

In addition, competitors may manufacture and sell our potential products in those foreign countries where we have not filed for patent protection or where patent protection may be unavailable, not obtainable or ultimately not enforceable. In addition, even where patent protection is obtained, third-party competitors may challenge our patent claims in the various patent offices, for example via opposition in the European Patent Office or reexamination or interference proceedings in the United States Patent and Trademark Office (USPTO). The ability of such competitors to sell such products in the United States or in foreign countries where we have obtained patents is usually governed by the patent laws of the countries in which the product is sold.

Merck, which has sublicensed our Ebola vaccine product candidate, has received correspondence from Yale University asserting that it owns certain intellectual property rights with respect to the Ebola vaccine that they assert, among other things, may need to be licensed by Merck. We also received correspondence from Yale University relating to the research and construction of the Ebola vaccine product by our licensor PHAC. If Merck were required to pay royalties to Yale University, that could result in a reduction of Merck's royalty obligations to us. If Merck otherwise suffered damages as a result of claims by Yale University, it is possible that Merck could seek indemnification from us.

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair our ability to access additional capital and/or cost us significant funds to defend.

We intend to rely on patent rights for our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets.

We rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain regulatory exclusivity and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technologies and product candidates.

We have sought to protect our proprietary position by filing patent applications related to our technologies and product candidates that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable, or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection or data exclusivity, for our product candidates, we may not be able to compete effectively, and our business and results of operations would be harmed.

We may not have sufficient patent term protections for our product candidates to effectively protect our business.

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Additional patent terms may be available through a patent term adjustment process, resulting from the USPTO delays during prosecution. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from generic medications.

Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data exclusivity terms of our product candidates. We will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our product candidates for an extended period after regulatory approval, if any, which would negatively impact our business, financial condition, results of operations, and prospects. If we do not have sufficient patent terms or regulatory exclusivity to protect our product candidates, our business and results of operations will be adversely affected.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office has developed regulations and procedures to govern administration of the Leahy-Smith Act, but many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first-inventor-to-file provisions, only became effective 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We may be subject to litigation with respect to the ownership and use of intellectual property that will be costly to defend or pursue and uncertain in its outcome.

Our success also will depend, in part, on our refraining from infringing patents or otherwise violating intellectual property owned or controlled by others. Pharmaceutical companies, biotechnology companies, universities, research institutions, and others may have filed patent applications or have received, or may obtain, issued patents in the United States or elsewhere relating to aspects of our technology. It is uncertain whether the issuance of any third-party patents will require us to alter our products or processes, obtain licenses, or cease certain activities. Some third-party applications or patents may conflict with our issued patents or pending applications. Any such conflict could result in a significant reduction of the scope or value of our issued or licensed patents.

In addition, if patents issued to other companies contain blocking, dominating or conflicting claims and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative non-infringing technology and cease practicing those activities, including potentially manufacturing or selling any products deemed to infringe those patents. If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from pursuing the development and commercialization of certain of our potential products. Our failure to obtain a license to any technology that we may require to commercialize our products on favorable terms may have a material adverse impact on our business, financial condition and results of operations.

Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of the proprietary rights of others. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any third party would be found to infringe our patents.

In addition, if our competitors filed patent applications in the United States that claim technology also claimed by us, and such applications were filed before the Leahy-Smith Act took effect, we may have to participate in interference proceedings to determine priority of invention. These proceedings, if initiated by the USPTO, could result in substantial cost to us, even if the eventual outcome is favorable to us. Such proceedings can be lengthy; are costly to defend and involve complex questions of law and fact, the outcomes of which are difficult to predict. An adverse outcome with respect to a third party claim or in an interference proceeding could subject us to significant liabilities, require us to license disputed rights from third parties, or require us to cease using such technology, any of which could have a material adverse effect on our business, financial condition and results of operations.

We also rely on trade secrets to protect technology, especially where patent protection is not believed to be appropriate or obtainable or where patents have not issued. We attempt to protect our proprietary technology and processes, in part, with confidentiality agreements and assignment of invention agreements with our employees and confidentiality agreements with our consultants and certain contractors. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We may fail in certain circumstances to obtain the necessary confidentiality agreements, or their scope or term may not be sufficiently broad to protect our interests.

If our trade secrets or other intellectual property becomes known to our competitors, it could result in a material adverse effect on our business, financial condition and results of operations. To the extent that we or our consultants or research collaborators use intellectual property owned by others in work for us, disputes may also arise as to the rights to related or resulting know-how and inventions.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States.

These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries, particularly some developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Our Exposure to Litigation

We are exposed to potential product liability or similar claims, and insurance against these claims may not be available to us at a reasonable rate in the future.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and commercial sale of human therapeutic products. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper administration of the product candidate, or other factors. Many of these patients are already seriously ill and are therefore particularly vulnerable to further illness or death. In addition, healthy volunteers in our indoximod clinical trial or our Ebola vaccine product candidate clinical trial may suffer, or perceive themselves to suffer, personal injury or death related to the Ebola vaccine product candidates and may initiate legal action against us.

We carried clinical trial liability insurance in the amount of $5.0 million through July 9, 2019 in the aggregate for claims related to our product candidates other than our Ebola vaccine product candidate. We currently carry clinical trial liability insurance in the amount of $10.0 million in the aggregate for claims related to our Ebola vaccine product candidate. We additionally currently carry clinical trial coverage in lower aggregate amounts in local markets where our clinical trials are conducted on a selective, trial by trial basis. There can be no assurance that we will be able to maintain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance. In addition, there can be no assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any future products by us or our collaborators.

On December 9, 2014, the HHS declared our Ebola vaccine product candidate covered under the Public Readiness and Emergency Preparedness Act. This declaration provides immunity under U.S. law against legal claims

related to the manufacturing, testing, development, distribution and administration of our vaccine candidate. It does not generally provide immunity for a claim brought in a court outside the United States.

Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

We are involved in a securities class-action litigation and are at risk of additional similar litigation in the future that could divert management's attention and adversely affect our business and could subject us to significant liabilities.

In the past, securities class action litigation has often been brought against a company following periods of volatility in the market price of securities. We are a party to the securities class action litigation described in Part II, Item 1 of this Quarterly Report on Form 10-Q under the heading "Legal Proceedings." The defense of this litigation may increase our expenses and divert our management's attention and resources and any unfavorable outcome could have a material adverse effect on our business and results of operations. Any adverse determination in this litigation, or any amounts paid to settle this litigation could require that we make significant payments. In addition, we may in the future be the target of other securities class actions or similar litigation.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and could decline significantly.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including those described elsewhere in this "Risk Factors" section of this Quarterly Report on Form 10-Q and the following:

- new products, product candidates or new uses for existing products introduced or announced by our strategic collaborators, or our competitors, and the timing of these introductions or announcements;
- actual or anticipated results from and any delays in our clinical trials, as well as results of regulatory reviews relating to the approval of our product candidates;
- variations in the level of expenses related to any of our product candidates or clinical development programs, including those relating to the timing of invoices from, and other billing practices of, our clinical research organizations and clinical trial sites;
- expenses related to, or our ability or perceived ability to secure, an adequate supply of any future products approved for commercial sale;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures and capital commitments;
- the commercial or clinical success or failure, or perceived success or failure, of our collaborators, including Merck;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;

- media attention, or changes in media attention, given to cancer and cancer treatment, the recent Ebola epidemic and efforts to develop treatments and vaccines for Ebola, or any other condition or disease that our product candidates are being developed to treat;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- the financial projections we may provide to the public, and any changes in these projections or our failure to meet these projections;
- deviations from securities analysts' estimates or the impact of other analyst rating downgrades by any securities analysts who follow our common stock;
- other events or factors, including those resulting from political uncertainty, war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. We are currently party to the securities class action litigation described in Part II, Item 1 of this Quarterly Report on Form 10-Q under the heading "Legal Proceedings." This litigation and others like it that could be brought against us in the future could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of September 30, 2019, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 33.8% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after September 30, 2019. These stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our Board of Directors, future issuances of our common stock or other securities, declarations of dividends on our common stock and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock. In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares may be distributed and subsequently voted.

Our amended and restated bylaws designates the state courts in the State of Delaware of, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against us or our directors, officers, or employees.

Our amended and restated bylaws (***"Bylaws"***) provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only

if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on behalf of the corporation; (2) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, other employee or stockholder of the corporation to the corporation or to the corporation's stockholders; (3) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or the Bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or (4) any action asserting a claim governed by the internal affairs doctrine. This choice of forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, or the Exchange Act, or any claim for which the federal courts have exclusive jurisdiction.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits. Furthermore, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to meet compliance obligations.

As a public company, we incur significant legal, accounting and other expenses to comply with reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), as well as rules subsequently implemented by the SEC and The Nasdaq Global Market. Meeting the requirements of these rules and regulations entails significant legal and financial compliance costs, makes some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel devote a substantial amount of time to these compliance requirements. In addition, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to publish a report by our management on our internal control over financial reporting. To achieve compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which has been both costly and challenging. To maintain compliance on an ongoing basis, we will need to dedicate internal resources, engage outside consultants and adopt a detailed work plan. Despite our effort, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We do not expect to pay any cash dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking only cash dividends should not purchase our common stock.

Provisions in our certificate of incorporation, our by-laws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our certificate of incorporation, our by-laws or Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management,

including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. These provisions include:

- the division of our Board of Directors into three classes with staggered, three-year terms;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to call special meetings;
- limitations on the ability of stockholders to remove directors or amend our by-laws; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person that together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

The holdings of our stockholders may be diluted, and the prices of our securities may decrease, by the exercise of outstanding stock options or by future issuances of securities by us.

We may issue additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock or the exercise of stock options would dilute existing investors and could adversely affect the price of our securities. In addition, such securities may have rights senior to the rights of securities held by existing investors.

Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Code.

Sections 382 and 383 of the Code limit a corporation’s ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. A Section 382 ownership change can, therefore, result in significantly greater tax liabilities than a corporation would incur in the absence of such a change, and any increased liabilities could adversely affect the corporation’s business, results of operations, financial condition and cash flow.

Based on Section 382 ownership change analyses, we believe that, from our inception through June 30, 2019, we experienced Section 382 ownership changes in September 2001 and March 2003, and BPS experienced Section 382 ownership changes in January 2006 and January 2011. These ownership changes limited our ability to utilize federal net operating loss carryforwards and certain other tax attributes that accrued prior to the respective ownership changes of us and our subsidiaries and may continue to limit our ability to utilize such attributes in the future.

Additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders.

Accounting pronouncements may impact our reported results of operations and financial position.

U.S. GAAP and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new pronouncements or the application of existing pronouncements to changes in our business could significantly alter our reported financial statements and results of operations.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following exhibits are filed with this Form 10-Q or incorporated herein by reference to the document set forth next to the exhibit listed below. Where so indicated, exhibits that were previously filed are incorporated by reference.

	Incorporated By Reference				
Exhibit Number	Description	Form	Filing Date	Number	Filed Herewith
2.1	Agreement and Plan of Merger and Reorganization, dated September 30, 2019, by and among NewLink Genetics Corporation, Cyclone Merger Sub, Inc and Lumos Pharma, Inc.	8-K	9/30/2019	2.1	
2.2	Form of Support Agreement, by and between NewLink Genetics Corporation and its directors and officers and by and between NewLink Genetics Corporation and Stine Seed Farm, Inc.	8-K	9/30/2019	2.2	
3.1	Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2	Certificate of Amendment to Restated Certificate of Incorporation filed on May 10, 2013	8-K	5/14/2013		

3.1						
3.3	Amended and Restated Bylaws	8-K	9/30/2019	3.1		
4.1	Form of the Registrant’s Common Stock Certificate	S-1/A	10/26/2011	4.1		
4.2	Amended and Restated Investor Rights Agreement by and between the Registrant and certain holders of the Registrant’s capital stock dated as of December 1, 2010	10-Q	5/10/2012	4.3		
10.1	Separation Agreement by and between the Registrant and Charles J. Link, Jr. dated August 3, 2019					
10.2	Transition Agreement, by and between NewLink Genetics Corporation and Nicholas Vahanian, dated September 27, 2019	8-K			X	

9/30/2019

10.3
Employment Agreement, by and between NewLink Genetics Corporation and Carl Langren, dated September 30, 2019

8-K

9/30/2019

10.4
Employment Agreement, by and between NewLink Genetics Corporation and Eugene Kennedy, dated

8-K

9/30/2019

10.5
Employment Agreement, by and between NewLink Genetics Corporation and Brad Powers, dated September

8-K

9/30/2019

10.6
Employment Agreement, by and between NewLink Genetics Corporation and Lori Lawley, dated September 30, 2019

8-K

9/30/2019

10.7
Form of Lock-Up Agreement

8-K

9/30/2019

31.1
Certification of principal executive officer required by Rule 13a-14(a) / 15d-14(a)

X

31.2
Certification of principal financial officer required by Rule 13a-14(a) / 15d-14(a)

X

32.1#
Section 1350 Certification

X

101.INS‡
XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

X

Exhibit Number	Description	Incorporated By Reference			Filed Herewith
		Form	Filing Date	Number	
101.SCH‡	XBRL Taxonomy Extension Schema Document				X
101.CAL‡	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF‡	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB‡	XBRL Taxonomy Extension Label Linkbase Document				X

101.PRE‡	XBRL Taxonomy Extension Presentation Linkbase Document	

X

"The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NewLink Genetics Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing."

‡ Filed herewith electronically.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

NEWLINK GENETICS CORPORATION

By: /s/ Brad J. Powers
Brad J. Powers
General Counsel
(Principal Executive Officer)
Date: November 6, 2019

By: /s/ Carl W. Langren
Carl W. Langren
Chief Financial Officer and Secretary
(Principal Financial Officer)
Date: November 6, 2019

Annex F

STIFEL | Investment Banking

September 30, 2019

Board of Directors of
NewLink Genetics Corporation (in its capacity as such)

2503 South Loop Drive
Ames, IA 50010

Members of the Board of Directors:

Stifel, Nicolaus & Company, Incorporated ("Stifel" or "we") has been advised that NewLink Genetics Corporation, a Delaware corporation (the "Company"), Cyclone Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company ("Merger Sub"), and Lumos Pharma, Inc., a Delaware corporation (the "Target"), propose to enter into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") pursuant to which, among other things, (i) Merger Sub will be merged with and into the Target (the "Merger") with the Target being the surviving company in the Merger and becoming a wholly-owned subsidiary of the Company, (ii) the holders of outstanding shares of capital stock of the Target ("Target Capital Stock") outstanding immediately prior to the Merger (excluding shares of Target Capital Stock held by the Target (as treasury stock or otherwise) and Dissenting Shares (as defined in the Merger Agreement)) shall, in the aggregate, be entitled to receive a number of shares of Common Stock of the Company, par value $0.01 per share ("Company Common Stock"), equal to the number of shares of Company Common Stock outstanding immediately prior to the Effective Time (as defined in the Merger Agreement) (excluding shares of Company Common Stock underlying options, warrants and rights, or otherwise reserved for issuance, immediately prior to the Effective Time), with each such share being automatically converted into the right to receive a number of shares of Company Common Stock equal to the amount determined pursuant to the Company Charter Amendment (as defined in the Merger Agreement) together with any cash payments made in lieu of fractional shares (the "Target Stock Consideration"), and (iii) each option to purchase shares of Common Stock of the Target outstanding and unexercised immediately prior to the Effective Time, whether or not vested (the "Target Options"), shall be converted into and become an option to purchase shares of Company Common Stock on the terms set forth in the Merger Agreement (the "Target Option Consideration," and together with the Target Stock Consideration, the "Merger Consideration"). The terms and conditions of the Merger are more completely described in the Merger Agreement.

The Board of Directors of the Company (the "Board"), in its capacity as such, has requested Stifel's opinion, as investment bankers, as to the fairness, from a financial point of view, as of the date of such opinion, to the Company of the Merger Consideration to be paid by the Company in the Merger pursuant to the Merger Agreement (the "Opinion").

In rendering our Opinion, we have, among other things:

(i) Reviewed the financial terms of the Merger contained in the Agreement;

(ii) Discussed the Merger and related matters with the Company's counsel and reviewed a draft copy of the Agreement, dated September 30, 2019, such draft being the latest draft provided to us;

(iii) Reviewed and analyzed certain internal financial analyses, financial projections, reports and other information concerning the Company and the Target prepared by the management of the Company, including projections for the Company and the Target provided by the management of the Company and reflecting the probabilities of technical success determined by the management of the Company (the "Company Projections" and the "Target Projections", respectively), and utilized per instruction of the Company;

(iv) Reviewed and discussed with the Company's management certain other publicly available information concerning the Company and the Target;

(v) Reviewed certain other non-publicly available information concerning the Company and held discussions with the Company's management regarding recent developments;

(vi) Held discussions with the Company's management, regarding estimates of certain cost savings, operating synergies, merger charges and the pro forma financial impact of the Merger on the Company;

(vii) Reviewed the reported prices and trading activity of the Company Common Stock;

(viii) Reviewed and analyzed, based on the Target Projections, the cash flows generated by the Target on a stand-alone basis to determine the present value of those discounted cash flows;

(ix) Reviewed and analyzed certain financial terms of the initial public offerings of certain companies that Stifel deemed relevant to the Target;

(x) Reviewed and analyzed certain publicly available information concerning the terms of selected merger and acquisition transactions that we considered relevant to our analysis;

(xi) Reviewed and analyzed certain publicly available financial and stock market data relating to selected public companies that we deemed relevant to our analysis;

(xii) Participated in certain discussions and negotiations between representatives of the Company and the Target;

(xiii) Conducted such other financial studies, analyses and investigations and considered such other information as we deemed necessary or appropriate for purposes of our Opinion; and

(xiv) Took into account our assessment of general economic, market and financial conditions and our experience in other transactions, as well as our experience in securities valuations and our knowledge of the Company's industry generally.

In rendering our Opinion, we have relied upon and assumed, without independent verification, the accuracy and completeness of all of the financial and other information that was provided to Stifel by or on behalf of the Company or the Target, or that was otherwise reviewed by Stifel, and have not assumed any responsibility for independently verifying any of such information. With respect to the financial forecasts supplied to us by the Company (including, without limitation, the Company Projections and the Target Projections and potential cost savings and operating synergies which may be realized as a result of the Merger), we have assumed, at the direction of the Company, that they were reasonably prepared on the basis reflecting the best currently available estimates and judgments of the management of the Company as to the future operating and financial performance of the Company and the Target, as applicable, and that they provided a reasonable basis upon which we could form our Opinion. Such forecasts and projections were not prepared with the expectation of public disclosure. All such projected financial information is based on numerous variables and assumptions that are inherently uncertain, including, without limitation, factors related to general economic and competitive conditions. Accordingly, actual results could vary significantly from those set forth in such projected financial information. Stifel has relied on this projected financial information without independent verification or analyses and does not in any respect assume any responsibility for the accuracy or completeness thereof. We have also assumed for purposes of our Opinion that, as of the date hereof, all out-of-the-money options to purchase shares of Company Common Stock and all out-of-the-money Target Options are without value.

We also assumed that there were no material changes in the assets, liabilities, financial condition, results of operations, business or prospects of either the Company or the Target since the date of the last financial statements of each company made available to us. We did not make or obtain any independent evaluation, appraisal or physical inspection of either the Company's or the Target's assets or liabilities, nor have we been furnished with any such evaluation or appraisal. Estimates of values of companies and assets do not purport to be appraisals or necessarily reflect the prices at which companies or assets may actually be sold. Because such estimates are inherently subject to uncertainty, Stifel assumes no responsibility for their accuracy.

We have assumed, with your consent, that there are no factors that would delay or subject to any adverse conditions any necessary regulatory or governmental approval and that all conditions to the Merger will be satisfied and not waived. In addition, we have assumed that the definitive Merger Agreement will not differ materially from the draft we reviewed. We have also assumed that the Merger will be consummated substantially on the terms and conditions

described in the Merger Agreement, without any waiver of material terms or conditions by the Company or any other party and without any anti-dilution or other adjustment to the Merger Consideration, and that obtaining any necessary regulatory approvals or satisfying any other conditions for consummation of the Merger will not have an adverse effect on the Company, the Target or the Merger. We have assumed that the Merger will be consummated in a manner that complies with the applicable provisions of the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, and all other applicable federal and state statutes, rules and regulations. We have further assumed that the Company has relied upon the advice of its counsel, independent accountants and other advisors (other than Stifel) as to all legal, financial reporting, tax, accounting and regulatory matters with respect to the Company, the Merger and the Merger Agreement.

Our Opinion is limited to whether the Merger Consideration to be paid by the Company in the Merger pursuant to the Merger Agreement is fair to the Company, from a financial point of view, and does not address any other terms, aspects or implications of the Merger, including, without limitation, the form or structure of the Merger, any consequences of the Merger on the Company, its stockholders, creditors or any other constituency or otherwise, or any terms, aspects or implications of any voting, support, stockholder or other agreements, arrangements or understandings contemplated or entered into in connection with the Merger or otherwise. Our Opinion also does not consider, address or include: (i) any other strategic alternatives currently (or which have been or may be) contemplated by the Board or the Company; (ii) the legal, tax or accounting consequences of the Merger on the Company or the holders of the Company's securities; (iii) the fairness of the amount or nature of any compensation to any of the Company's officers, directors or employees, or class of such persons, relative to the compensation to the holders of the Company's securities; (iv) the effect of the Merger on, or the fairness of the consideration to be received by, holders of any class of securities of the Company, or any class of securities of any other party to any transaction contemplated by the Merger Agreement; or (v) whether the Company has sufficient cash, available lines of credit or other sources of funds to enable it to pay the cash component of the Merger Consideration. Furthermore, we are not expressing any opinion herein as to the prices, trading range or volume at which the Company's securities will trade following public announcement or consummation of the Merger.

Our Opinion is necessarily based on economic, market, financial and other conditions as they exist on, and on the information made available to us by or on behalf of the Company or its advisors, or information otherwise reviewed by Stifel, as of the date of this Opinion. It is understood that subsequent developments may affect the conclusion reached in this Opinion and that Stifel does not have any obligation to update, revise or reaffirm this Opinion, except in accordance with the terms and conditions of Stifel's engagement letter agreement with the Company. Our Opinion is for the information of, and directed to, the Board for its information and assistance in connection with its consideration of the financial terms of the Merger. Our Opinion does not constitute a recommendation to the Board as to how the Board should vote on the Merger or to any stockholder of the Company as to how any such stockholder should vote at any stockholders' meeting at which the Merger is considered, or whether or not any stockholder of the Company or the Target should enter into a voting, support, stockholders' or affiliates' agreement with respect to the Merger, or exercise any dissenters' or appraisal rights that may be available to such stockholder. In addition, the Opinion does not compare the relative merits of the Merger with any other alternative transactions or business strategies which may have been available to the Company and does not address the underlying business decision of the Board or the Company to proceed with or effect the Merger.

We are not legal, tax, regulatory or bankruptcy advisors. We have not considered any potential legislative or regulatory changes currently being considered or recently enacted by the United States Congress, the Securities and Exchange Commission (the "SEC") or any other regulatory bodies, or any changes in accounting methods or generally accepted accounting principles that may be adopted by the SEC or the Financial Accounting Standards Board. Our Opinion is not a solvency opinion and does not in any way address the solvency or financial condition of the Company or the Target either before or after the Merger.

Stifel, as part of its investment banking services, is regularly engaged in the independent valuation of businesses and securities in connection with mergers, acquisitions, underwritings, sales and distributions of listed and unlisted securities, private placements and valuations for estate, corporate and other purposes. We have acted as financial advisor to the Company in connection with the Merger and will receive a fee for our services, a substantial portion

of which is contingent upon the completion of the Merger (the "Advisory Fee"). We have also acted as a financial advisor to the Board and will receive a fee upon the delivery of this Opinion, which is not contingent upon consummation of the Merger, but which is creditable against any Advisory Fee. We will not receive any other significant payment or compensation contingent upon the successful consummation of the Merger. In addition, the Company has agreed to reimburse certain of our expenses and indemnify us for certain liabilities arising out of our engagement. In October 2017, Stifel acted as joint book-running manager for the Company's offering of 5,750,000 shares of common stock for which it was paid customary fees (the "2017 Offering"). Other than the 2017 Offering, there are no material relationships that existed during the two years prior to the date of this Opinion or that are mutually understood to be contemplated in which any compensation was received or is intended to be received as a result of the relationship between Stifel and any party to the Merger. Stifel may seek to provide investment banking services to the Company or its affiliates (including the Target) in the future, for which we would seek customary compensation. In the ordinary course of business, Stifel, its affiliates and their respective clients may transact in the equity securities of the Company and may at any time hold a long or short position in such securities.

Stifel's Fairness Opinion Committee has approved the issuance of this Opinion. Our Opinion may not be published or otherwise used or referred to, nor shall any public reference to Stifel be made, without our prior written consent, except in accordance with the terms and conditions of Stifel's engagement letter agreement with the Company.

Based upon and subject to the foregoing, we are of the opinion that, as of the date hereof, the Merger Consideration to be paid by the Company in the Merger pursuant to the Merger Agreement is fair to the Company, from a financial point of view.

Very truly yours,

/s/ STIFEL, NICOLAUS & COMPANY, INCORPORATED
STIFEL, NICOLAUS & COMPANY, INCORPORATED

Annex G

SUPPORT AGREEMENT

This **SUPPORT AGREEMENT** (this "***Agreement***"), dated as of September [•], 2019, is by and between Lumos Pharma, Inc. ("***Lumos***"), and the Person set forth on Schedule A hereto (the "***Stockholder***").

WHEREAS, as of the date hereof, the Stockholder is the holder of the number of shares of common stock, par value $0.01 per share ("***Common Stock***"), of NewLink Genetics Corporation, a Delaware corporation ("***NewLink***"), set forth opposite the Stockholder's name on Schedule A (all such shares set forth on Schedule A, together with any shares of Common Stock that are hereafter issued to or otherwise acquired or owned by the Stockholder prior to the termination of this Agreement being referred to herein as the "***Subject Shares***");

WHEREAS, Lumos, Cyclone Merger Sub, Inc., a Delaware corporation and a direct wholly owned subsidiary of NewLink ("***Merger Sub***") and NewLink propose to enter into an Agreement and Plan of Merger and Reorganization, dated as of the date hereof (the "***Merger Agreement***"), which provides, among other things, for the merger of Merger Sub with and into Lumos, with Lumos continuing as the surviving corporation (the "***Merger***"), upon the terms and subject to the conditions set forth in the Merger Agreement (capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed to such terms in the Merger Agreement); and

WHEREAS, as a condition to its willingness to enter into the Merger Agreement, Lumos has required that the Stockholder, and as an inducement and in consideration therefor, the Stockholder (in the Stockholder's capacity as a holder of the Subject Shares) has agreed to, enter into this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth below and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, do hereby agree as follows:

ARTICLE I

VOTING AGREEMENT; GRANT OF PROXY

The Stockholder hereby covenants and agrees that:

1.1. **Voting of Subject Shares**. At every meeting of the holders of Company Capital Stock (the "***NewLink Stockholders***"), however called, and at every adjournment or postponement thereof (or pursuant to a written consent if the NewLink Stockholders act by written consent in lieu of a meeting), the Stockholder shall, or shall cause the holder of record on any applicable record date to, be present (in person or by proxy) and to vote the Subject Shares (a) in favor of (i) the amendment of NewLink's certificate of incorporation to effect the Nasdaq Reverse Split, (ii) the issuance of shares of NewLink Common Stock to Lumos's stockholders in connection with the Contemplated Transactions; (iii) the change of control of NewLink resulting from the Merger pursuant to the Nasdaq rules, if required, and (iv) any proposal submitted to the NewLink Stockholders in accordance with Section 14A of the Exchange Act and the applicable SEC rules issued thereunder, seeking advisory approval of NewLink Stockholders for a non-binding, advisory vote to approve certain compensation that may become payable to NewLink's named executive officers in connection with the completion of the Merger, if applicable; and (b) against any Acquisition Proposal.

1.2. **No Inconsistent Arrangements**. Except as provided hereunder or under the Merger Agreement, the Stockholder shall not, directly or indirectly, (a) create any Encumbrance other than restrictions imposed by applicable Laws or pursuant to this Agreement on any Subject Shares, (b) transfer, sell, assign, gift or otherwise dispose of (collectively, "***Transfer***"), or enter into any contract with respect to any Transfer of the Subject Shares or any interest therein, (c) grant or permit the grant of any proxy, power of attorney or other authorization in or with respect to the Subject Shares, (d) deposit or permit the deposit of the Subject Shares into a voting trust or enter into a voting agreement or arrangement with respect to the Subject Shares, or (e) take any action that, to the knowledge of the Stockholder, would make any representation or warranty of the Stockholder herein untrue or incorrect in any material respect, or have the effect of preventing the Stockholder from performing its obligations hereunder. Notwithstanding the foregoing, (i) the Stockholder may (A) make transfers of the Subject Shares as charitable gifts or donations, (B) make transfers or dispositions of the Subject Shares to any trust for the direct or indirect benefit of the Stockholder or the immediate family of the Stockholder, (C) make transfers or dispositions of the Subject Shares by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member

of the immediate family of the Stockholder, (D) make transfers of the Subject Shares to stockholders, direct or indirect affiliates (within the meaning set forth in Rule 405 under the Securities Act), current or former partners (general or limited), members or managers of the Stockholder, as applicable, or to the estates of any such stockholders, affiliates, partners, members or managers, or to another corporation, partnership, limited liability company or other business entity that controls, is controlled by or is under common control with the Stockholder, (E) transfers that occur by operation of law pursuant to a qualified domestic order or in connection with a divorce settlement, (F) transfers or dispositions not involving a change in beneficial ownership, (G) if the Stockholder is a trust, make transfers or dispositions to any beneficiary of the Stockholder or the estate of any such beneficiary, provided that, in each case, the transferee agrees in writing to be bound by the terms and conditions of this Agreement and either the Stockholder or the transferee provides NewLink with a copy of such agreement promptly upon consummation of any such Transfer and (ii) the Stockholder may take all actions reasonably necessary to consummate the Contemplated Transactions, including, without limitation, effecting the Nasdaq Reverse Split.

1.3. **No Exercise of Appraisal Rights; Waivers**. The Stockholder hereby (a) waives and agrees not to exercise any dissenters' or appraisal rights, or other similar rights, with respect to any Subject Shares that may arise in connection with the Contemplated Transactions and (b) agrees that it will not bring, commence, institute, maintain, prosecute, participate in or voluntarily aid any action, claim, suit or cause of action, in law or in equity, in any court or before any Governmental Body, which (i) challenges the validity of or seeks to enjoin the operation of any provision of this Agreement or (ii) alleges that the execution and delivery of this Agreement by the Stockholder, or the approval of the Merger Agreement by the NewLink Board of Directors, breaches any fiduciary duty of the NewLink Board of Directors or any member thereof; *provided*, *that* the Stockholder may defend against, contest or settle any such action, claim, suit or cause of action brought against the Stockholder that relates solely to the Stockholder's capacity as a director, officer or securityholder of NewLink.

1.4. **Documentation and Information**. The Stockholder shall permit and hereby authorizes NewLink and Lumos to publish and disclose in all documents and schedules filed with the SEC, and any other disclosure document that NewLink or Lumos reasonably determines to be required by applicable law in connection with the Merger and any transactions contemplated by the Merger Agreement, the Stockholder's identity and ownership of the Subject Shares and the nature of the Stockholder's commitments and obligations under this Agreement; provided that NewLink or Lumos, as the case may be, shall afford the Stockholder reasonable advance notice to review and comment on such disclosure. NewLink is an intended third-party beneficiary of this Section 1.4.

1.5. **Irrevocable Proxy**. The Stockholder hereby revokes (or agrees to cause to be revoked) any proxies that the Stockholder has heretofore granted with respect to the Subject Shares. The Stockholder hereby irrevocably appoints Lumos as attorney-in-fact and proxy for and on behalf of the Stockholder, for and in the name, place and stead of the Stockholder, to: (a) attend any and all meetings of NewLink Stockholders held for the matters addressed in Section 1.1, (b) vote, express consent or dissent or issue instructions to the record holder to vote the Subject Shares solely in furtherance of the provisions of Section 1.1 at any and all meetings of NewLink Stockholders or in connection with any action sought to be taken by written consent of NewLink Stockholders without a meeting and (c) grant or withhold, or issue instructions to the record holder to grant or withhold, consistent with the provisions of Section 1.1, all written consents with respect to the Subject Shares at any and all meetings of NewLink Stockholders or in connection with any action sought to be taken by written consent of NewLink Stockholders without a meeting, in any case solely in furtherance of the provisions of Section 1.1. Lumos agrees not to exercise the proxy granted herein for any purpose other than the purposes described in this Agreement. The foregoing proxy shall be deemed to be a proxy coupled with an interest, is irrevocable (and as such shall survive and not be affected by the death, incapacity, mental illness or insanity of the Stockholder, as applicable) until the termination of the Merger Agreement and shall not be terminated by operation of law or upon the occurrence of any other event other than the termination of this Agreement pursuant to Section 4.2. The Stockholder authorizes such attorney and proxy to substitute any other Person to act hereunder, to revoke any substitution and to file this proxy and any substitution or revocation with the Secretary of NewLink. The Stockholder hereby affirms that the proxy set forth in this Section 1.5 is given in connection with and granted in consideration of and as an inducement to Lumos to enter into the Merger Agreement and that such proxy is given to secure the obligations of the Stockholder under Section 1.1. The proxy set forth in this Section 1.5 is executed and intended to be irrevocable, subject, however, to its automatic termination upon the termination of this Agreement pursuant to Section 4.2. With respect to any Subject Shares that are owned beneficially by the Stockholder but are not held of record by the Stockholder, the Stockholder shall take all action necessary to cause the record holder of such Subject Shares to grant the irrevocable proxy and take all other actions provided for in this Section 1.5 with respect to such Subject Shares.

1.6. **No Solicitation of Transactions**. The Stockholder shall not knowingly, directly or indirectly, through any officer, director, agent or otherwise, (a) solicit, initiate, respond to or knowingly take any action to facilitate or encourage any inquiries or the communication, making, submission or announcement of any Acquisition Proposal or Acquisition Inquiry or take any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (b) enter into or participate in any discussions or negotiations with any Person with respect to any Acquisition Proposal or Acquisition Inquiry; (c) furnish any information regarding such party to any Person in connection with, in response to, relating to or for the purpose of assisting with or facilitating an Acquisition Proposal or Acquisition Inquiry; or (d) approve, endorse or recommend any Acquisition Proposal. The Stockholder hereby represents and warrants that he, she or it has read Section 4.4 of the Merger Agreement and agrees not to engage in any actions prohibited thereby.

1.7. **No Ownership Interest**. Nothing contained in this Agreement will be deemed to vest in Lumos any direct or indirect ownership or incidents of ownership of or with respect to the Subject Shares. All rights, ownership and economic benefits of and relating to the Subject Shares will remain and belong to Stockholder, and Lumos will have no authority to manage, direct, superintend, restrict, regulate, govern or administer any of the policies or operations of NewLink or exercise any power or authority to direct Stockholder in the voting of any of the Subject Shares, except as otherwise expressly provided herein with respect to the Subject Shares and except as otherwise expressly provided in the Merger Agreement.

ARTICLE II

REPRESENTATIONS AND WARRANTIES OF THE STOCKHOLDER

The Stockholder represents and warrants to Lumos that:

2.1. **Organization; Authorization; Binding Agreement**. The Stockholder, if not a natural person, is duly incorporated or organized, as applicable, validly existing and in good standing under the laws of its jurisdiction of incorporation or organization. The Stockholder has full legal capacity and power, right and authority to execute and deliver this Agreement and to perform his, her or its obligations hereunder and to consummate the transactions contemplated hereby. This Agreement has been duly and validly executed and delivered by the Stockholder, and constitutes a valid and binding obligation of the Stockholder enforceable against the Stockholder in accordance with its terms, subject to (a) laws of general application relating to bankruptcy, insolvency and the relief of debtors and (b) laws of general application relating to bankruptcy, insolvency, the relief of debtors, fraudulent transfer, reorganization, moratorium and other similar laws of general applicability relating to or affecting creditor's rights (the "***Enforceability Exceptions***").

2.2. **Ownership of Subject Shares; Total Shares**. The Stockholder is the record or beneficial owner (as defined in Rule 13d-3 under the Exchange Act) of the Subject Shares and has good and marketable title to the Subject Shares free and clear of any Encumbrances (including any restriction on the right to vote or otherwise transfer the Subject Shares), except (a) as provided hereunder, (b) pursuant to any applicable restrictions on transfer under the Securities Act, and (c) subject to any risk of forfeiture with respect to any shares of Common Stock granted to the Stockholder under an employee benefit plan of NewLink. The Subject Shares listed on Schedule A opposite the Stockholder's name constitute all of the shares of Common Stock owned by the Stockholder as of the date hereof. No Person has any contractual or other right or obligation to purchase or otherwise acquire any of the Subject Shares.

2.3. **Voting Power**. The Stockholder has full voting power, with respect to the Subject Shares, and full power of disposition, full power to issue instructions with respect to the matters set forth herein and full power to agree to all of the matters set forth in this Agreement, in each case, with respect to all of the Subject Shares. None of the Subject Shares are subject to any proxy, voting trust or other agreement or arrangement with respect to the voting of the Subject Shares except as provided hereunder.

2.4. **Reliance**. The Stockholder has had the opportunity to review the Merger Agreement and this Agreement with counsel of the Stockholder's own choosing. The Stockholder understands and acknowledges that Lumos is entering into the Merger Agreement in reliance upon the Stockholder's execution, delivery and performance of this Agreement.

2.5. **Absence of Litigation**. With respect to the Stockholder, as of the date hereof, there is no action, suit, investigation or proceeding pending against, or, to the knowledge of the Stockholder, threatened in writing against, the Stockholder or any of the Stockholder's properties or assets (including the Subject Shares) that could reasonably be expected to prevent, delay or impair the ability of the Stockholder to perform its obligations hereunder or to consummate the transactions contemplated hereby.

2.6. **No Conflicts**. Neither the execution and delivery of this Agreement, nor the consummation of the transactions contemplated hereby, nor compliance with the terms hereof, will violate, conflict with or result in a breach of, or constitute a default (with or without notice or lapse of time or both) under any provision of, any trust agreement, loan or credit agreement, note, bond, mortgage, indenture, lease or other agreement, instrument, permit, concession, franchise, license, judgment, order, notice, decree, statute, law, ordinance, rule or regulation applicable to the Stockholder or to the Stockholder's property or assets.

ARTICLE III

REPRESENTATIONS AND WARRANTIES OF LUMOS

Lumos represents and warrants to the Stockholder that:

3.1. **Organization; Authorization**. Lumos is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Delaware. The consummation of the transactions contemplated hereby is within Lumos's corporate powers and have been duly authorized by all necessary corporate actions on the part of Lumos. Lumos has full power and authority to execute, deliver and perform this Agreement.

3.2. **Binding Agreement**. This Agreement has been duly authorized, executed and delivered by Lumos and constitutes a valid and binding obligation of Lumos enforceable against Lumos in accordance with its terms, subject to the Enforceability Exceptions.

ARTICLE IV

MISCELLANEOUS

4.1. **Notices**. All notices, requests and other communications to either party hereunder shall be in writing (including facsimile transmission or electronic mail) and shall be given, (a) if to Lumos, in accordance with the provisions of the Merger Agreement and (b) if to the Stockholder, to the Stockholder's address, electronic mail address or facsimile number set forth on a signature page hereto, or to such other address, electronic address or facsimile number as the Stockholder may hereafter specify in writing to Lumos for the purpose by notice to Lumos.

4.2. **Termination**. This Agreement shall terminate automatically, without any notice or other action by any Person, upon the earlier of (a) the termination of the Merger Agreement in accordance with its terms and (b) the Effective Time. Upon termination of this Agreement, neither party shall have any further obligations or liabilities under this Agreement; *provided*, *however*, that (i) nothing set forth in this Section 4.2 shall relieve either party from liability for any breach of this Agreement prior to termination hereof, and (ii) the provisions of this Article IV shall survive any termination of this Agreement.

4.3. **Amendments and Waivers**. Any provision of this Agreement may be amended or waived if such amendment or waiver is in writing and is signed, in the case of an amendment, by Stockholder and Lumos, in the case of a waiver, by the party against whom the waiver is to be effective. No failure or delay by either party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege.

4.4. **Binding Effect; Benefit; Assignment**. The provisions of this Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and assigns. Except as set forth in Section 1.4, no provision of this Agreement is intended to confer any rights, benefits, remedies, obligations or liabilities hereunder upon any person other than the parties hereto and their respective successors and assigns. Neither party may assign, delegate or otherwise transfer any of its rights or obligations under this Agreement without the consent of the other party hereto, except that Lumos may transfer or assign its rights and obligations under this Agreement, in whole or from time to time in part, to one or more of its Affiliates at any time; provided, that such transfer or assignment shall not relieve Lumos of any of its obligations hereunder.

4.5. **Governing Law; Jurisdiction**. This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of Laws. In any action or proceeding between any of the parties arising out of or relating to this Agreement, each of the parties: (a) irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware or, to the extent that neither of the foregoing courts has jurisdiction, the Superior Court of the State of Delaware; (b) agrees that all claims in respect of such action or proceeding shall be heard and determined exclusively in accordance with clause (a) of this Section 4.5; (c) waives any objection to laying venue in any such action or proceeding in such courts; (d) waives any objection that such courts are an inconvenient forum or do not have jurisdiction over any party; and (e) irrevocably and unconditionally waives the right to trial by jury.

4.6. **Counterparts**. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by all parties by facsimile or electronic transmission in .PDF format shall be sufficient to bind the parties to the terms and conditions of this Agreement.

4.7. **Entire Agreement**. This Agreement constitutes the entire agreement and supersedes all prior agreements and understandings, both written and oral, among or between any of the parties with respect to the subject matter hereof and thereof.

4.8. **Severability**. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions of this Agreement or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any term or provision of this Agreement is invalid or unenforceable, the parties hereto agree that the court making such determination will have the power to limit such term or provision, to delete specific words or phrases or to replace such term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be valid and enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the parties hereto agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term or provision.

4.9. **Specific Performance**. Any and all remedies herein expressly conferred upon a party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such party, and the exercise by a party of any one remedy will not preclude the exercise of any other remedy. The parties hereto agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof in any federal or state court located in the State of Delaware, this being in addition to any other remedy to which they are entitled at law or in equity, and each of the parties hereto waives any bond, surety or other security that might be required of any other party with respect thereto.

4.10. **Construction**.

(a) For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; the masculine gender shall include the feminine and neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include masculine and feminine genders.

(b) The parties hereto agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not be applied in the construction or interpretation of this Agreement.

(c) As used in this Agreement, the words “include” and “including,” and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation.”

(d) Except as otherwise indicated, all references in this Agreement to “Sections,” “Articles,” and “Schedules” are intended to refer to Sections or Articles of this Agreement and Schedules to this Agreement, respectively.

The bold-faced headings contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

4.11. **Further Assurances**. Each of the parties hereto will execute and deliver, or cause to be executed and delivered, all further documents and instruments and use their respective reasonable best efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary under applicable Laws to perform their respective obligations as expressly set forth under this Agreement.

4.12. **Capacity as Stockholder**. The Stockholder signs this Agreement solely in the Stockholder's capacity as a Stockholder of NewLink, and not in the Stockholder's capacity as a director, officer or employee of NewLink or any of its Subsidiaries or in the Stockholder's capacity as a trustee or fiduciary of any employee benefit plan or trust. Notwithstanding anything herein to the contrary, nothing herein shall in any way restrict a director or officer of NewLink in the exercise of his or her fiduciary duties as a director or officer of NewLink or in his or her capacity as a trustee or fiduciary of any employee benefit plan or trust or prevent or be construed to create any obligation on the part of any director or officer of NewLink or any trustee or fiduciary of any employee benefit plan or trust from taking any action in his or her capacity as such director, officer, trustee or fiduciary.

4.13. **No Agreement Until Executed**. Irrespective of negotiations among the parties or the exchanging of drafts of this Agreement, this Agreement shall not constitute or be deemed to evidence a contract, agreement, arrangement or understanding between the parties hereto unless and until (a) the board of directors of NewLink has approved, for purposes of any applicable anti-takeover laws and regulations, and any applicable provision of NewLink's organizational documents, the Merger, (b) the Merger Agreement is executed by all parties thereto, and (c) this Agreement is executed by all parties hereto.

(SIGNATURE PAGE FOLLOWS)

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the date first written above.

LUMOS PHARMA, INC.

By: _____

Name:

Title:

STOCKHOLDER

_____

(Print Name of Stockholder)

_____

(Signature)

_____

(Name and Title of Signatory, if Signing on Behalf of an Entity)

[Signature Page to Support Agreement]

Schedule A

Name of Stockholder	No. Shares of Common Stock

Annex H

NewLink Genetics Corporation

Lock-Up Agreement

[•], 2019

This Lock-Up Agreement (this "***Agreement***") is executed in connection with the Agreement and Plan of Merger and Reorganization (the "***Merger Agreement***") by and among NewLink Genetics Corporation (the "***Parent***"), Cyclone Merger Sub, Inc., ("***Merger Sub***"), and Lumos Pharma, Inc. (the "***Company***"), dated as of [•], 2019. Capitalized terms used herein but not defined shall have the meanings ascribed to such terms in the Merger Agreement.

In connection with, and as an inducement to, the parties entering into the Merger Agreement and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the undersigned, by executing this Agreement, agrees that, without the prior written consent of the Parent, during the period commencing at the Effective Time and continuing until the end of the Lock-Up Period (as hereinafter defined), the undersigned will not: (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of or lend, directly or indirectly, any shares of Common Stock of Parent (the "***Parent Common Stock***") or any securities convertible into, exercisable or exchangeable for or that represent the right to receive Parent Common Stock (including without limitation, Parent Common Stock which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the Securities and Exchange Commission and securities which may be issued upon exercise of a stock option or warrant) whether now owned or hereafter acquired (the "***Securities***"); (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Parent Common Stock or such other securities, in cash or otherwise; (3) grant any proxies or powers of attorney with respect to any Securities, deposit any Securities into a voting trust or enter into a voting agreement or similar arrangement or commitment with respect to any Securities, other than the grant of any proxies to any officer of Parent in connection with the Parent Stockholders' Meeting or (4) publicly disclose the intention to do any of the foregoing (each of the foregoing restrictions, the "***Lock-Up Restrictions***").

The Lock-Up Restrictions shall automatically terminate and cease to be effective on the date that is one-hundred and eighty (180) days after the Effective Time. The period during which the Lock-Up Restrictions apply to the Securities shall be deemed the "***Lock-Up Period***" with respect thereto.

The undersigned agrees that the Lock-Up Restrictions preclude the undersigned from engaging in any hedging or other transaction with respect to any then-subject Securities which is designed to or which reasonably could be expected to lead to or result in a sale or disposition of such Securities even if such Securities would be disposed of by someone other than the undersigned. Such prohibited hedging or other transactions would include without limitation any short sale or any purchase, sale or grant of any right (including without limitation any put or call option) with respect to such Securities or with respect to any security that includes, relates to, or derives any significant part of its value from such Securities.

Notwithstanding the foregoing, the undersigned may transfer any of the Securities (i) as a *bona fide* gift or gifts or charitable contribution(s), (ii) to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned, (iii) if the undersigned is a corporation, partnership, limited liability company, trust or other business entity (1) to another corporation, partnership, limited liability company, trust or other business entity that is a direct or indirect affiliate (as defined in Rule 405 promulgated under the Securities Act) of the undersigned or (2) as distributions of shares of Parent Common Stock or any security convertible into or exercisable for Parent Common Stock to limited partners, limited liability company members or stockholders of the undersigned or holders of similar equity interests in the undersigned, (iv) if the undersigned is a trust, to the beneficiary of such trust, (v) by testate succession or intestate succession, (vi) to any immediate family member, any investment fund, family partnership, family limited liability company or other entity controlled or managed by the undersigned, (vii) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (vi), (viii) to Parent in a transaction exempt from Section 16(b) of the Exchange Act upon a vesting event of the Securities or upon the exercise of options or warrants to purchase Parent Common Stock on a "cashless" or "net exercise" basis or to cover tax withholding obligations of the undersigned in connection with such vesting or

exercise (but for the avoidance of doubt, excluding all manners of exercise that would involve a sale in the open market of any securities relating to such options or warrants, whether to cover the applicable aggregate exercise price, withholding tax obligations or otherwise), (ix) to Parent in connection with the termination of employment or other termination of a service provider and pursuant to agreements in effect as of the Effective Time whereby Parent has the option to repurchase such shares or securities, (x) acquired by the undersigned in open market transactions after the Effective Time, (xi) pursuant to a bona fide third party tender offer, merger, consolidation or other similar transaction made to all holders of the Parent's capital stock involving a Change of Control of the Parent, provided that in the event that such tender offer, merger, consolidation or other such transaction is not completed, the Securities shall remain subject to the restrictions contained in this Agreement, or (xii) pursuant to an order of a court or regulatory agency; *provided*, in the case of clauses (i)-(vii), that (A) such transfer shall not involve a disposition for value and (B) the transferee agrees in writing with Parent to be bound by the terms of this Agreement. For purposes of this Agreement, "***immediate family***" shall mean any relationship by blood, marriage or adoption, not more remote than first cousin and "***Change of Control***" shall mean the consummation of any bona fide third party tender offer, merger, consolidation or other similar transaction the result of which is that any "person" (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of more than 50% of total voting power of the voting stock of the Parent; provided that, for the avoidance of doubt, the consummation of the Contemplated Transactions shall not constitute a Change of Control for purposes of this Agreement.

In addition, the foregoing restrictions shall not apply to (i) the exercise of stock options (x) that would expire during the Lock-Up Period or (y) other than Company Options that are converted into and become options to purchase Parent Common Stock pursuant to Section 5.4(a) of the Merger Agreement, that are granted pursuant to Parent Stock Plans existing following the Effective Time, including in each case the "net" exercise of such options in accordance with their terms and the surrender of Parent Common Stock in lieu of payment in cash of the exercise price and any tax withholding obligations due as a result of such exercise; *provided* that it shall apply to any of the Securities issued upon such exercise, or (ii) the establishment of any contract, instruction or plan (a "***Plan***") that satisfies all of the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act; *provided* that no sales of the Securities shall be made pursuant to such a Plan prior to the expiration of the Lock-Up Period, and such a Plan may only be established if no public announcement of the establishment or existence thereof and no filing with the Securities and Exchange Commission or other regulatory authority in respect thereof or transactions thereunder or contemplated thereby, by the undersigned, Parent or any other person, shall be required, and no such announcement or filing is made voluntarily, by the undersigned, Parent or any other person, prior to the expiration of the applicable Lock-Up Period. In furtherance of the foregoing, Parent and its transfer agent and registrar are hereby authorized to decline to make any transfer of shares of Parent Common Stock if such transfer would constitute a violation or breach of this Agreement.

The undersigned understands that the Securities shall bear the following or substantially similar legends, whether in book-entry or certificated form (in addition to any other legends required by law or any agreement to which any such Seller is a party):

> *"THE SECURITIES REPRESENTED HEREBY ARE SUBJECT TO AN AGREEMENT BY THE REGISTERED HOLDER HEREOF THAT RESTRICTS THE TRANSFER OR SALE OF THESE SHARES BEFORE THE DATE THAT IS 180-DAYS AFTER THE EFFECTIVE TIME*. COPIES OF SUCH AGREEMENT MAY BE OBTAINED UPON WRITTEN REQUEST OF THE SECRETARY OF THE ISSUER"

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Agreement and that upon request, the undersigned will execute any additional documents reasonably necessary to ensure the validity or enforcement of this Agreement. All authority herein conferred or agreed to be conferred and any obligations of the undersigned shall be binding upon the successors, assigns, heirs or personal representatives of the undersigned.

The undersigned understands that the undersigned shall be released from all obligations under this Agreement if the Merger Agreement is terminated prior to the Effective Time pursuant to its terms, upon the date of such termination.

In the event that, during the Lock-Up Period, the Parent releases or waives any prohibition set forth in this Lock-Up Agreement on the transfer of Securities held by any of the stockholders of the Parent or the Company or any of their respective affiliates who receive shares from one or more of such stockholders during the Lock-Up Period

as permitted by this Lock-Up Agreement, the same percentage of the total number of Securities held by the undersigned as the percentage of the total number of outstanding Securities held by such stockholder that are the subject of such waiver shall be immediately and fully released on the same terms from the applicable prohibition(s) set forth herein. Notwithstanding the foregoing, the provisions of this paragraph will not apply if (1) the release or waiver is effected solely to permit a transfer not involving a disposition for value and (2) the transferee agrees in writing to be bound by the same terms described in this Lock-Up Agreement to the extent and for the duration that such terms remain in effect at the time of transfer. The Parent shall use commercially reasonable efforts to promptly notify the undersigned of each such release (provided that the failure to provide such notice shall not give rise to any claim or liability against the Parent or the Company).

The undersigned understands that Parent, the Merger Sub and the Company are entering into the Merger Agreement in reliance upon this Agreement.

This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware.

[Signature Page Follows]

This Agreement, and any certificates, documents, instruments and writings that are delivered pursuant hereto, constitutes the entire agreement and understanding of the Parent, the Company and the undersigned in respect of the subject matter hereof and supersedes all prior understandings, agreements or representations by or among the Parent, the Company and the undersigned, written or oral, to the extent they relate in any way to the subject matter hereof.

Very truly yours,

_____

Printed Name of Holder

By: _____

Signature

_____

Printed Name of Person Signing

(and indicate capacity of person signing if signing as custodian, trustee, or on behalf of an entity)

Annex I

CERTIFICATE OF AMENDMENT

TO THE

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

NEWLINK GENETICS CORPORATION

NewLink Genetics Corporation (the "**Corporation**"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, as amended (the "**DGCL**"), hereby certifies as follows:

A. The name of the Corporation is NewLink Genetics Corporation. The date of filing of the original Certificate of Incorporation of the Corporation with the Secretary of State of the State of Delaware was June 4, 1999, and such Certificate of Incorporation was restated on November 16, 2011 and further amended on May 10, 2013.

B. This Certificate of Amendment to the Amended and Restated Certificate of Incorporation (the "**Certificate of Amendment**") amends the Corporation's Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on November 16, 2011, as amended on May 10, 2013 (as amended, the "**Prior Certificate**"), and has been duly adopted by the Corporation's Board of Directors and stockholders in accordance with the provisions of Section 242 of the DGCL.

C. Article IV, Section A of the Prior Certificate is hereby amended and restated to read in its entirety as follows:

"**A.** This corporation is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the corporation is authorized to issue is 80,000,000 shares. 75,000,000 shares shall be Common Stock, each having a par value of one cent ($0.01). 5,000,000 shares shall be Preferred Stock, each having a par value of one cent ($0.01).

At [ ] Eastern Time on the date of filing of this Certificate of Amendment to the Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware each
( ) shares of Common Stock outstanding immediately prior to such filing shall be automatically reclassified into one (1) share of Common Stock. The aforementioned reclassification shall be referred to collectively as the "Reverse Split."

The Reverse Split shall occur without any further action on the part of the Company or stockholders of the Company and whether or not certificates representing such stockholders' shares prior to the Reverse Split are surrendered for cancellation. No fractional interest in a share of Common Stock shall be deliverable upon the Reverse Split. All shares of Common Stock (including fractions thereof) issuable upon the Reverse Split held by a holder prior to the Reverse Split shall be aggregated for purposes of determining whether the Reverse Split would result in the issuance of any fractional share. Any fractional share resulting from such aggregation upon the Reverse Split shall be rounded down to the nearest whole number. Each holder who would otherwise be entitled to a fraction of a share of Common Stock upon the Reverse Split (after aggregating all fractions of a share to which such stockholder would otherwise be entitled) shall, in lieu thereof, be entitled to receive a cash payment in an amount equal to the fraction to which the stockholder would otherwise be entitled multiplied by the closing price of the Company's Common Stock as reported on the Nasdaq Stock Market on the date of the filing of this Certificate of Amendment to the Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (adjusted to reflect the Reverse Split, as applicable). The Company shall not be obliged to issue certificates evidencing the shares of Common Stock outstanding as a result of the Reverse Split unless and until the certificates evidencing the shares held by a holder prior to the Reverse Split are either delivered to the Company or its transfer

agent, or the holder notifies the Company or its transfer agent that such certificates have been lost, stolen or destroyed and executes an agreement satisfactory to the Company to indemnify the Company from any loss incurred by it in connection with such certificates."

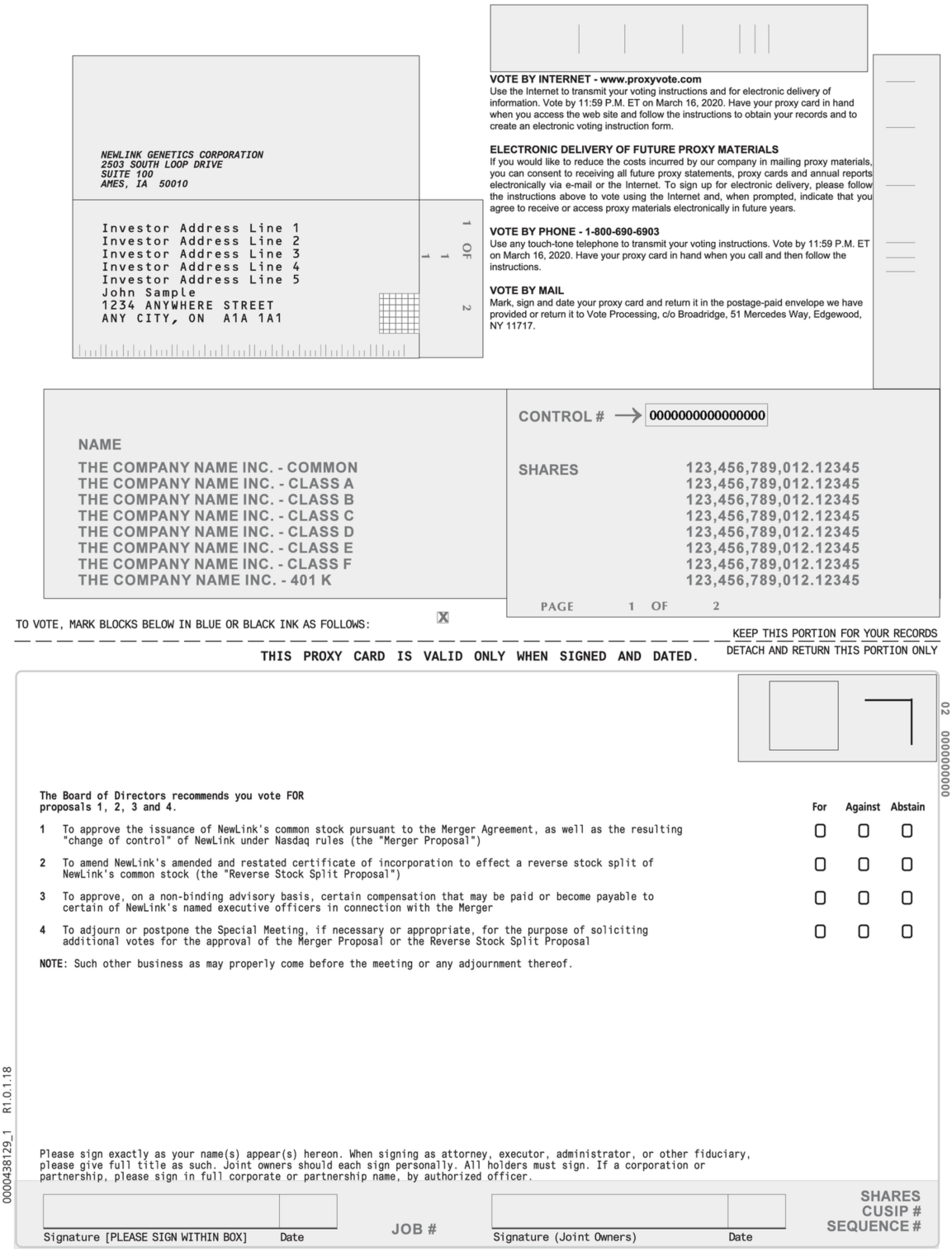
D. The Certificate of Amendment of the Prior Certificate so adopted reads in full as set forth above and is hereby incorporated by reference. All other provisions of the Prior Certificate remain in full force and effect.

IN WITNESS WHEREOF, NewLink Genetics Corporation has caused this Certificate of Amendment to be signed by , a duly authorized officer of the Corporation, on , 20 .

NEWLINK GENETICS CORPORATION

By: _____
Name:
Title:

[Signature Page to Amendment to Certificate of Incorporation]



NEWLINK GENETICS CORPORATION
2503 SOUTH LOOP DRIVE
SUITE 100
AMES, IA 50010

Investor Address Line 1
Investor Address Line 2
Investor Address Line 3
Investor Address Line 4
Investor Address Line 5
John Sample
1234 ANYWHERE STREET
ANY CITY, ON A1A 1A1

1 OF 2

VOTE BY INTERNET - www.proxyvote.com
Use the Internet to transmit your voting instructions and for electronic delivery of information. Vote by 11:59 P.M. ET on March 16, 2020. Have your proxy card in hand when you access the web site and follow the instructions to obtain your records and to create an electronic voting instruction form.

ELECTRONIC DELIVERY OF FUTURE PROXY MATERIALS
If you would like to reduce the costs incurred by our company in mailing proxy materials, you can consent to receiving all future proxy statements, proxy cards and annual reports electronically via e-mail or the Internet. To sign up for electronic delivery, please follow the instructions above to vote using the Internet and, when prompted, indicate that you agree to receive or access proxy materials electronically in future years.

VOTE BY PHONE - 1-800-690-6903
Use any touch-tone telephone to transmit your voting instructions. Vote by 11:59 P.M. ET on March 16, 2020. Have your proxy card in hand when you call and then follow the instructions.

VOTE BY MAIL
Mark, sign and date your proxy card and return it in the postage-paid envelope we have provided or return it to Vote Processing, c/o Broadridge, 51 Mercedes Way, Edgewood, NY 11717.

NAME

THE COMPANY NAME INC. - COMMON
THE COMPANY NAME INC. - CLASS A
THE COMPANY NAME INC. - CLASS B
THE COMPANY NAME INC. - CLASS C
THE COMPANY NAME INC. - CLASS D
THE COMPANY NAME INC. - CLASS E
THE COMPANY NAME INC. - CLASS F
THE COMPANY NAME INC. - 401 K

CONTROL # → 0000000000000000

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PAGE 1 OF 2

TO VOTE, MARK BLOCKS BELOW IN BLUE OR BLACK INK AS FOLLOWS: X

KEEP THIS PORTION FOR YOUR RECORDS
DETACH AND RETURN THIS PORTION ONLY

THIS PROXY CARD IS VALID ONLY WHEN SIGNED AND DATED.

02 0000000000

The Board of Directors recommends you vote FOR proposals 1, 2, 3 and 4.

		For	Against	Abstain
1	To approve the issuance of NewLink's common stock pursuant to the Merger Agreement, as well as the resulting "change of control" of NewLink under Nasdaq rules (the "Merger Proposal")	☐	☐	☐
2	To amend NewLink's amended and restated certificate of incorporation to effect a reverse stock split of NewLink's common stock (the "Reverse Stock Split Proposal")	☐	☐	☐
3	To approve, on a non-binding advisory basis, certain compensation that may be paid or become payable to certain of NewLink's named executive officers in connection with the Merger	☐	☐	☐
4	To adjourn or postpone the Special Meeting, if necessary or appropriate, for the purpose of soliciting additional votes for the approval of the Merger Proposal or the Reverse Stock Split Proposal	☐	☐	☐

NOTE: Such other business as may properly come before the meeting or any adjournment thereof.

Please sign exactly as your name(s) appear(s) hereon. When signing as attorney, executor, administrator, or other fiduciary, please give full title as such. Joint owners should each sign personally. All holders must sign. If a corporation or partnership, please sign in full corporate or partnership name, by authorized officer.

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Signature [PLEASE SIGN WITHIN BOX] Date

JOB #

Signature (Joint Owners) Date

SHARES
CUSIP #
SEQUENCE #

Important Notice Regarding the Availability of Proxy Materials for the Special Meeting: The Notice & Proxy Statement is/are available at www.proxyvote.com

NEWLINK GENETICS CORPORATION
Special Meeting of Stockholders
March 17, 2020, 9:00 A.M. Local Time
This proxy is solicited by NewLink's Board of Directors

The stockholder hereby appoints Carl W. Langren, Bradley J. Powers and Ryan D. Trytten, or any of them, as proxies, each with the power to appoint his substitute, and hereby authorizes them to represent and to vote, as designated on the reverse side of this ballot, all of the shares of common stock of NEWLINK GENETICS CORPORATION that the stockholder is entitled to vote at the Special Meeting of Stockholders to be held on March 17, 2020 at 9:00 a.m. Local Time, at ISU Economic Development Core Facility, 1805 Collaboration Place, Ames, IA 50010, and any adjournment or postponement thereof.

THIS PROXY, WHEN PROPERLY EXECUTED WILL BE VOTED AS DIRECTED BY THE UNDERSIGNED. IF NO SUCH DIRECTIONS ARE MADE, THIS PROXY WILL BE VOTED FOR PROPOSALS 1, 2, 3 AND 4 AND IN THE DISCRETION OF THE PROXIES WITH RESPECT TO SUCH OTHER BUSINESS AS MAY PROPERLY COME BEFORE THE MEETING.

NEWLINK'S BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS A VOTE "FOR" PROPOSALS 1 - 4.

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Continued and to be signed on reverse side