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, 2023.

OR

☐ **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

LUMOS PHARMA, INC.
(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.)
4200 Marathon Blvd #200 **Austin, Texas**	**78756**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(512) 215-2630**

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	LUMO	The Nasdaq Stock 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 ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ 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 ☐

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 ☐

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 ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
Emerging growth company ☐	

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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant, based on the closing sale price of the registrant's common stock June 30, 2023, as reported by the Nasdaq Global Market, was $21.5 million.

As of March 1, 2024, there were 8,107,121 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2024 Annual Meeting of Shareholders, to be held on May 31, 2024, which will be filed within 120 days of December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

		Page
Part I		
Item 1.	Business	5
Item 1A.	Risk Factors	25
Item 1B.	Unresolved Staff Comments	65
Item 1C.	Cybersecurity	66
Item 2.	Properties	67
Item 3.	Legal Proceedings	67
Item 4.	Mine Safety Disclosures	67
Part II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchase of Equity Securities	68
Item 6.	[Reserved]	68
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	69
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	76
Item 8.	Financial Statements and Supplementary Data	77
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	99
Item 9A.	Controls and Procedures	99
Item 9B.	Other Information	99
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	97
Part III		
Item 10.	Directors, Executive Officers and Corporate Governance	100
Item 11.	Executive Compensation	100
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	100
Item 13.	Certain Relationships and Related Transactions, and Director Independence	100
Item 14.	Principal Accounting Fees and Services	100
Part IV		
Item 15.	Exhibits, Financial Statement Schedules	101
Item 16.	Form 10-K Summary	102
Signatures		

Cautionary Statement Regarding Forward-Looking Statements

This annual report on Form 10-K for the year ended December 31, 2023 (this "Annual Report") contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements involve risks and uncertainties and reflect our current views with respect to, among other things, future events and our financial performance. When used in this report, the words "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "expect," "indicate," "seek," "should," "would," and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. These forward-looking statements are not historical facts, and are based on current expectations, estimates and projections about our industry, management's beliefs and certain assumptions made by management, many of which, by their nature, are inherently uncertain and beyond our control. Accordingly, we caution you that any such forward-looking statements are not guarantees of future performance and are subject to risks, assumptions, estimates and uncertainties that are difficult to predict. Although we believe that the expectations reflected in these forward-looking statements are reasonable as of the date of this Annual Report, actual results may prove to be materially different from the results expressed or implied by the forward-looking statements.

Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to those summarized below:

- the development plan for our product candidate, the growth hormone secretagogue ibutamoren ("LUM-201");
- a weakened macroeconomic environment, including high inflation rates, and its impact on our business, including impacts to our operating costs and financial condition;
- our expectations regarding the potential benefits, activity, effectiveness and safety of our product candidates;
- our expectations regarding potential revenue generation, sources, and timing;
- the development plan for our existing pipeline and potential partnership and out-licensing opportunities;
- the timing of planned preclinical studies and clinical trials and availability of clinical data from such clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the timing of and our ability to obtain 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 intellectual property position;
- our ability to enter into strategic collaborations, licensing or other arrangements;
- our dependence on collaborators for developing, obtaining regulatory approval for and commercializing product candidates in the collaboration;
- our estimates regarding assets, liabilities, expenses, future revenues, capital requirements and needs for additional financing;
- plans to develop and commercialize our product candidates;
- our ability and plans to fund our operations;
- the rate and degree of market acceptance of any approved product candidates;
- the commercialization of any approved product candidates;
- the implementation of our business model and strategic plans for our business, technologies and product candidates;
- our reliance on third parties to conduct our preclinical studies or any future clinical trials;
- our ability to attract and retain qualified key management and technical personnel;
- the amount and timing of dividends or share repurchases, if any;
- our reliance on third-party supply and manufacturing partners to supply the materials and components for, and manufacture, our research and development, preclinical and clinical trial product supplies;
- the extent to which military conflict and any associated economic downturn, governmental regulations or restrictions may adversely impact our business, including impacts to our research, clinical trials, manufacturing and financial condition; and
- developments relating to our competitors or our industry.

For additional information regarding known material factors that could cause our actual results to differ from our projected results, please read (1) Part I, Item 1A. “Risk Factors” in this Annual Report, (2) our reports and registration statements filed from time to time with the Securities and Exchange Commission (the “SEC”), and (3) other public announcements we make from time to time. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

PART I

Item 1. BUSINESS

Overview

Lumos Pharma, Inc. is a clinical-stage biopharmaceutical company. References in this Annual Report to "us," "we," "our," the "Company," or "Lumos" are to Lumos Pharma, Inc. and its wholly-owned subsidiaries. With our principal executive offices located in Austin, Texas and additional executive and administrative offices located in Ames, Iowa, we are engaged in advancing our clinical program and focused on identifying, acquiring, developing, and commercializing novel products and new therapies for people with rare diseases on a global level, for which there is currently a significant unmet need for safe and effective therapies. Our common stock is listed on the Nasdaq Global Market ("Nasdaq") and trades under the ticker symbol "LUMO."

The Company entered into a business combination (the "Merger") between the Company, formerly known as NewLink Genetics Corporation ("NewLink"), Cyclone Merger Sub, Inc. ("Merger Sub"), a wholly owned subsidiary of NewLink, and Lumos Pharma, Inc., which has since been renamed "Lumos Pharma Sub, Inc." ("Private Lumos"). The Merger closed on March 18, 2020, and Merger Sub merged with and into Private Lumos, with Private Lumos surviving as a wholly-owned subsidiary of the Company.

After the consummation of the Merger, we have focused our efforts on the development of our sole product candidate, secretagogue ibutamoren ("LUM-201"), a potential oral therapy for idiopathic pediatric growth hormone deficiency ("PGHD") and other rare endocrine disorders.

Strategy

Our strategy is to identify, acquire, develop, and commercialize novel products for the treatment of rare diseases on a global scale, prioritizing direct commercialization in selected markets, beginning with the United States and seeking to enter into partnerships or licensing arrangements in other markets. The critical components of our business strategy include the following:

- continue focus on rare diseases with limited or no treatment options;
- focus on diseases and therapies with clear pathophysiology and mechanisms of action;
- leverage our experience and relationships to in-license promising product candidates from academic institutions, rare disease patient foundations, and/or 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, our goal is to be a leading rare disease drug company.

Our Product Candidate

LUM-201

Our pipeline is focused on the development of an orally administered small molecule, LUM-201, which is a growth hormone ("GH") secretagogue, also called ibutamoren, for rare endocrine disorders where injectable recombinant human growth hormone ("rhGH") is currently approved. LUM-201 is a tablet formulation that will be administered once daily.

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 recombinant growth hormone product injections. 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.

Overview of PGHD

The PGHD population consists of patients diagnosed with organic PGHD (a more severe GH deficiency) and idiopathic PGHD (a less severe GH deficiency). LUM-201 has been observed to stimulate endogenous GH secretion in patients who have a functional but reduced hypothalamic pituitary GH axis, also known as moderate or idiopathic PGHD patients. We believe that patients with idiopathic PGHD (i.e., those who have a functional but reduced hypothalamic pituitary GH axis) represent approximately 60% of PGHD patients and are expected to respond to LUM-201.

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 (radiation therapy for a 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 and improve body composition, enabling short children to achieve normal height and prevent complications that could involve metabolic abnormalities, cognitive deficits and reduced quality of life. The current standard of care for PGHD is limited to daily subcutaneous injections of rhGH with a treatment cycle lasting up to an average of seven years. Poor compliance with daily rhGH injections during treatment can result in an adverse impact on growth and body composition. In addition to the approval of Skytrofa in 2021, the FDA approved two new once-weekly injection products in 2023, Ngenla and Sogroya, that would reduce the number of injections over the course of treatment for a patient; however, based on our market research, we believe that many providers and patients will have a preference for an orally administered treatment, when available.

Clinical Trial Results and Development Plans

During the fourth quarter of 2020, we launched a program to study the effects of LUM-201 in PGHD and initiated our Phase 2 clinical trial ("OraGrowthH210 Trial" or the "Phase 2 Trial") with the opening of the initial sites participating in this study. The OraGrowthH210 Trial is a global multi-site randomized study evaluating orally administered LUM-201 at three dose levels (0.8, 1.6 and 3.2 mg/kg/day) against a standard dose of daily injectable rhGH in approximately 80 subjects diagnosed with idiopathic PGHD.

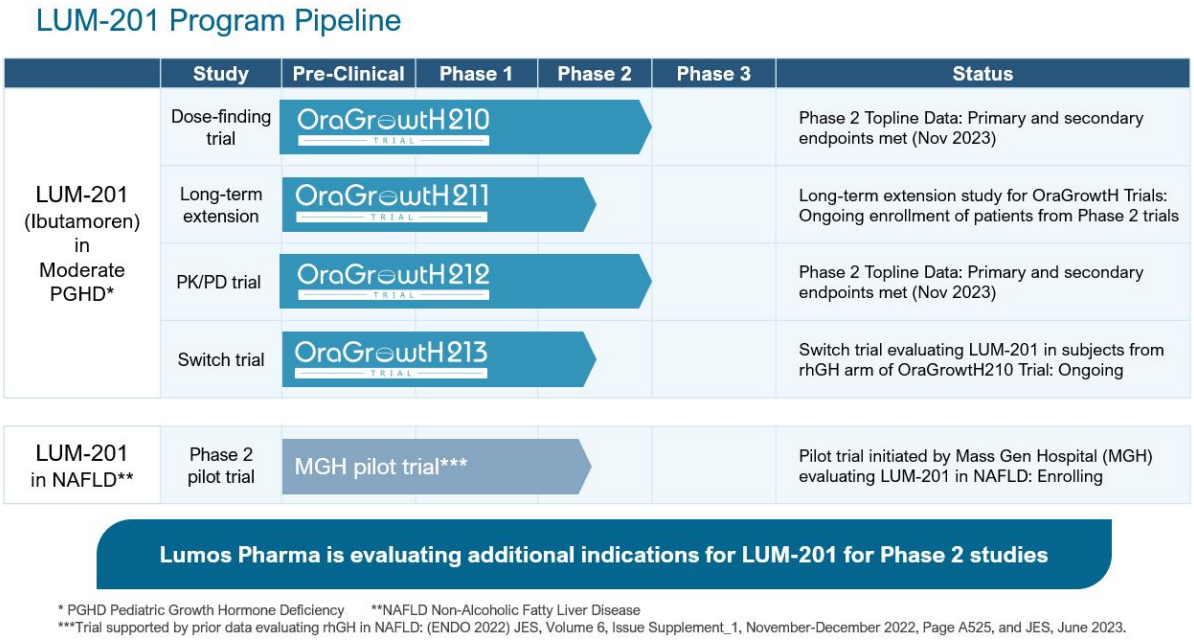
The primary endpoint of the study is preliminary validation of our predictive enrichment marker ("PEM") patient selection strategy as evidenced by the percentage of selected patients who grow in response to LUM-201. Each patient enrolled in our Phase 2 clinical trials was given a single dose of LUM-201 at the 0.8 mg/kg/day dose to determine if they meet the cut-off criteria for enrollment, which is a baseline insulin-like growth factor ("IGF-1") > 30 ng/ml and stimulated GH ≥5 ng/ml. The primary efficacy endpoint is annualized height velocity ("AHV") at six months on treatment with the prediction of growth of 8.3 to 8.6 cm/yr based on historical data for this moderate idiopathic population. Secondary endpoints include selection of a pediatric dose of LUM-201 for future studies including Phase 3 and determination of the degree of repeatability of the PEM selection process in PEM positive patients screened for participation in OraGrowthH210. Consistent with other Phase 2 trials in PGHD, OraGrowthH210 is not powered to show non-inferiority of AHV between Lum-201 and the control arm.

A second concurrent trial of LUM-201 in PGHD exploring the effects of the novel mechanism of action of LUM-201 in amplifying the pulsatile secretion of growth hormone (the "OraGrowthH212 Trial") was initiated in the second quarter of 2021. The OraGrowthH212 Trial in PGHD is being run in parallel with the OraGrowthH210 Trial. The OraGrowthH212 Trial is a single site, open-label trial evaluating the pharmacokinetic and pharmacodynamic ("PK/PD") effects of LUM-201 in up to 24 PGHD subjects at two different dose levels, 1.6 and 3.2 mg/kg/day. The objective of the OraGrowthH212 Trial is to confirm prior clinical data illustrating the increased pulsatile release of endogenous growth hormone unique to LUM-201 and its potential for this mechanism of action to contribute to efficacy in PGHD. Our OraGrowthH212 Trial is being conducted at a single specialized pediatric center with the capacity to conduct the more frequent sample acquisition and monitoring required for this type of clinical trial. Data from the OraGrowthH212 Trial may be supportive in future regulatory filings; however, this trial is not required for regulatory approval of LUM-201. The primary endpoint for this trial is six months of PK/PD and height velocity data in up to 24 subjects. As we announced on February 28, 2023, we completed enrollment for this trial with 22 subjects.

During the first quarter of 2022, we initiated our OraGrowthH213 Trial (the "OraGrowthH213 Trial," and together with the OraGrowthH210 Trial, the OraGrowthH211 Trial, and the OraGrowthH212 Trial, the "OraGrowthH Trials"), an open-label, multi-center, Phase 2 study evaluating the growth effects and safety of LUM-201 following 12 months of daily rhGH in up to 20 idiopathic PGHD subjects who have completed the OraGrowthH210 Trial. Subjects will be administered LUM-201 at a dose level of 3.2 mg/kg/day for up to 12 months.

We announced in November 2023 that our OraGrowtH210 and OraGrowtH212 Trials met all primary and secondary endpoints. Our OraGrowtH210 data demonstrated that the 1.6 mg/kg/day LUM-201 dose produced a mean AHV of 8.2 cm/yr at six months on treatment for moderate PGHD subjects, in line with historical data in moderate PGHD patients. Additionally, at twelve months on treatment, a durable effect was also observed with LUM-201 achieving AHV of 8.0 cm/yr at the 1.6 mg/kg dose, within the targeted 2 cm/yr margin of the comparator injectable rhGH arm. Data also provided preliminary validation of the PEM strategy, with prespecified primary and secondary outcomes met, de-risking our patient selection for our Phase 3 program. Data from the OraGrowtH212 Trial confirmed that LUM-201's unique pulsatile mechanism produces an increase in the growth rates while restoring growth hormone secretion and IGF-1 to within normal ranges. The safety profile for LUM-201 remained clean throughout both Phase 2 trials, with no safety concerns identified in either of our Phase 2 trials conducted thus far. This data supports advancing our plans to initiate a Phase 3 trial anticipated in the second half of 2024, dependent upon a successful FDA meeting, anticipated in the second quarter of 2024, and completion of a financing.

The graphic below depicts the clinical development plan for LUM-201.



Potential expansion of LUM-201 into additional indications

In May 2022, we announced a clinical collaboration with Massachusetts General Hospital ("MGH") to evaluate oral LUM-201 in nonalcoholic fatty liver disease ("NAFLD") in an investigator-initiated trial. This trial will evaluate a dose of 25 mg/day of LUM-201 in 10 men and women with NAFLD; this dose is supported by the large Phase 2 database of treatment of adults with LUM-201 by Merck, showing increases in growth hormone and IGF-1 from baseline through as long as 24 months, along with improvements in body composition. Enrollment in the trial is in process and four subjects have completed the trial. GH is a critical stimulator of lipolysis, and preclinical data suggest that amplifying GH secretion has the potential to reduce hepatic steatosis and prevent NAFLD progression. Enhancing the natural pulsatile release of GH has been shown clinically in short-term studies to be more efficacious in inducing lipolysis than continuous infusions of GH. The primary endpoints will be to determine the changes in intrahepatic lipid content, hepatic inflammation and fibrosis with GH augmentation as measured by H-MRS and Perspectum's LiverMultiScan®. Biopsies will be conducted on a subset of subjects to obtain additional information at the genetic and cellular level in this indication.

We approved an unsolicited grant application for this study and will supply LUM-201 for this pilot trial. Lumos has a pending application for a method-of-use patent for LUM-201 in NAFLD and retains intellectual property rights for LUM-201 in this indication.

We continue to explore our development path to expand into additional indications for LUM-201. Based on our initial review to date, we have narrowed our focus for the next indications to include Idiopathic Short Stature, with a focus on the Asia markets, and Prader Willi Syndrome, where we see an attractive global opportunity. We have prioritized our resources for

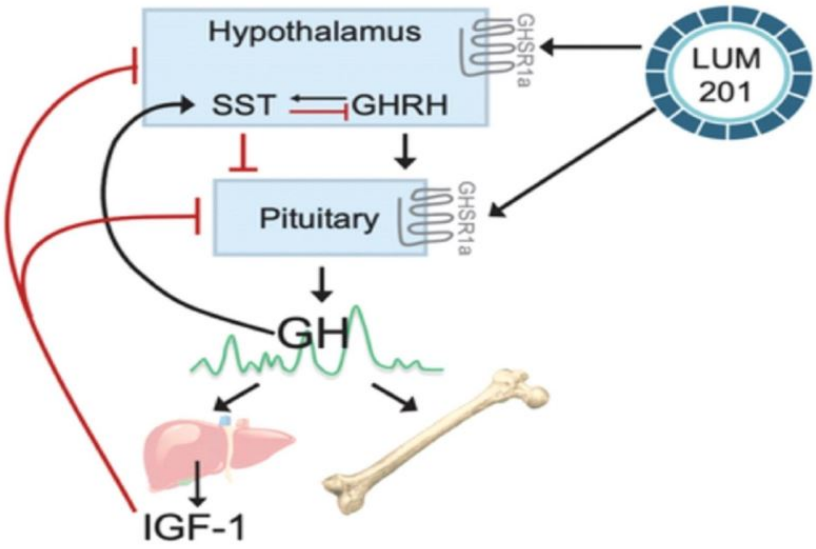
PGHD and currently plan to advance planning for Prader Willi Syndrome and Idiopathic Short Stature indications subject to securing additional funding for our LUM-201 Phase 3 trial.

Mechanism of action of LUM-201

LUM-201 stimulates GH via the GH secretagogue receptor (GHSR1a), also known as the ghrelin receptor. LUM-201 also suppresses the release of somatostatin, 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 both circulating levels of GH and its down-stream mediator IGF-1 which at supraphysiological levels feedbacks or negatively regulates additional release of GH from the pituitary, hence protecting against hyperstimulation of the pituitary.

LUM-201 has demonstrated stimulatory GH responses following oral administration in mice, rats, dogs, pigs, and humans. GHSR1a activation via LUM-201 binding induces GH release, as demonstrated in vitro in rat pituicytes (LUM-201 EC50 1.3 nM). In addition, the treatment of pituicytes with LUM-201 augments the effect of exogenous GHRH on GH secretion, as the two compounds synergistically stimulated GH release from rat pituitary cells, demonstrating distinct mechanisms of action.

The mechanism of action of LUM-201 is illustrated below.



Rare Disease Focus

Patient-focused drug development for rare diseases is the foundational focal point at Lumos. We are committed to developing potential therapies with the utmost urgency and care by advancing product candidates through approval by engaging, early and often, with patients to better understand their perspective during the continuum of the drug development process. We are dedicated to promoting a strong patient-centric philosophy among our partners and stakeholders and have initiated 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.

Market Demand

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. In addition to the approval of Skytrofa in 2021, the FDA approved two new once-weekly injection products in 2023, Ngenla and Sogroya,

that would reduce the number of injections over the course of treatment for a patient; however, based on our market research, we believe that many providers and patients will have a preference for an orally administered treatment, when available.

GH-deficient children who are fully in adherence with their daily injectable 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 adopted 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 GH treatments that would require less frequent injections, like Skytrofa. We believe that an oral treatment would help the idiopathic subset of PGHD patients achieve better treatment results through better treatment compliance than is typical for the current standard of care.

LUM-201 is intended to stimulate the release of endogenous GH in PGHD patients who are idiopathic and have a functional but reduced hypothalamic pituitary GH axis. We believe that the proportion that fits such criteria is approximately 60% of all PGHD 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.

Commercialization Strategy

We intend to commercialize LUM-201 for PGHD in markets for which marketing exclusivity or patent protection can be obtained, provided we receive regulatory marketing authorization (an "MA") 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. We have received Orphan Drug Designation ("ODD") in both territories, which is one source of exclusivity if approved. We may also target additional markets including China, Japan and Korea. We intend to seek ODD in additional countries at the appropriate time. Some territories, such as China, do not offer ODD exclusivity. In order to protect against generic product market intrusion in these markets we will seek patent protection through our existing PEM patent, our formulation patent, if granted, and possible future patent applications.

We currently have no sales, manufacturing, production or distribution capabilities. We expect 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. If one or more of our product candidates receive regulatory approval, we expect to establish a specialty sales organization with technical expertise and supporting distribution capabilities to co-promote and/or commercialize our product candidates. We may choose to work with third parties that have direct sales forces and established manufacturing, production and distribution systems, either to augment our own sales force and systems or in lieu of our own sales force and systems.

Patients with rare disorders are typically treated by a small number of specialists. As a result, we expect our commercial structure to be modest in size with an emphasis on supporting programs to expedite patient identification, diagnosis, and assistance to patients and healthcare providers to support market access relating to treatment and reimbursement support.

Competition

The development and commercialization of new therapeutic products is highly competitive. We face competition with respect to LUM-201 and will face competition with respect to any product candidates that we 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 our target patient group. These companies typically are well established and have extensive experience within our targeted indications. 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 our target indications.

We are developing our 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 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), 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.), as well as Skytrofa® (Ascendis Pharma), Nglena (OPCO Health, Inc., in collaboration with Pfizer), and Sogroya (Novo Nordisk), which are administered by weekly subcutaneous injection. These rhGH drugs, apart from Valtropin, Skytrofa, Nglena, and Sogroya, 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 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.

Intellectual Property

We have been assigned U.S. Patent Nos. 9763919, 10898472, 10105352 and 11234969 and European Patent Nos. 3939590 and 3352752, "Detecting and Treating Growth Hormone Deficiency." The patents are not due to expire in the United States or Europe before 2036 and have also been issued in Australia, Canada, Israel, Japan, South Korea, Hong Kong, Singapore, and Ukraine, with related patent applications pending in multiple other jurisdictions. More specifically, related patent applications have been filed by Ammonett Pharma LLC ("Ammonett") (such patent applications now owned by Lumos) in Brazil, Canada, China, the European Patent Office, New Zealand, and Singapore. The composition of matter patent for LUM-201 has expired and the chemical structure for LUM-201 is in the public domain. However, we have 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, 10105352 and 11234969 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.

We also have 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. We may elect to seek collaborations to develop LUM-201 for these indications in the future.

In November 2022, we filed a patent application titled "Compactable Oral Formulations of Ibutamoren," which contains claims directed to certain improved LUM-201 drug product formulations we intend to utilize in our LUM-201 Phase 3 trial and ultimately commercialize. The novel formulation takes advantage of unique properties of LUM-201, namely the ability to compress a desired quantity of drug product into a tablet smaller than typical tablets. We believe the compressed tablet will enable a commercial product offering well suited for the full range of potential patient preferences and will result in a reduced treatment burden for the patient population. The patent application is currently pending and if granted, would provide composition of matter protection through November 2042 for the commercialized version of LUM-201.

In February 2024, we filed a provisional patent application titled "Pharmaceutical Formulations for Maintaining Lean Muscle Mass During Weight Loss Treatment," which contains claims directed to the use of LUM-201 in combination with a glucagon-like peptide 1 ("GLP-1") receptor agonist or a dual GLP-1/glucose-dependent insulinotropic polypeptide ("GIP") agonist. This novel combination takes advantage of the unique properties of LUM-201, including inhibition of myostatin signaling, the ability to reverse diet-induced nitrogen wasting in humans, and the ability to generate sustained increases in serum levels of growth hormone, IGF-1 and IGF-binding protein-3. We believe this combination has the potential to improve GLP-1 treatment by minimizing reductions in lean mass while improving body composition by increasing the proportion of lean to fat mass. The provisional patent application has been filed and any patents granted, would provide protection through February 2044 for the combined therapies utilizing LUM-201 and GLP-1.

Orphan Drug Designation

LUM-201 received 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. Related patents have been issued in the European Union, Australia, Israel, Japan, South Korea, Hong Kong, Singapore, and Ukraine with related patent applications pending in multiple other jurisdictions.

License and Asset Purchase Agreement

In July 2018, we entered into an asset purchase agreement (the "APA") with Ammonett and acquired substantially all of the assets related to LUM-201, which Ammonett had licensed from Merck Sharpe and Dohme Corp. ("Merck") in October 2013 (the "Lumos Merck Agreement").

The Lumos Merck Agreement 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.

On August 12, 2020, we entered into Amendment No. 1 to the Lumos Merck Agreement with Merck (the "Lumos Merck Agreement Amendment"). Pursuant to the Lumos Merck Agreement Amendment, we obtained from Merck a worldwide, non-exclusive, sublicensable (subject to Merck's consent in the United States, specified major European countries and Japan, such consent not to be unreasonably withheld) license under the specified patents and know-how that are the subject of our exclusive license to develop, manufacture and commercialize LUM-201 for diagnostic purposes, excluding Autism Spectrum Disorders.

Under the APA, we paid Ammonett an upfront fee of $3.5 million in 2018. We may also incur development milestone payments totaling up to $17.0 million for achievement of specified milestones on the first indication that we pursue and up to $14.0 million for achievements of specified milestones on the second indication that we pursue, sales milestone payments totaling up to $55.0 million on worldwide product sales, and royalty payments based on worldwide product sales, as discussed below.

Under the Lumos Merck Agreement, we 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 $14.0 million for the first indication that we pursue and up to $8.5 million for the second indication that we pursue. Tiered sales milestone payments totaling up to $80.0 million are required on worldwide net product sales up to $1.0 billion, and substantial royalty payments based on product sales are required if product sales are achieved.

If product sales are ever achieved, we are 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 Merck License and thereafter until the expiration of the last patent assigned to us 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 us 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, we are obligated to use reasonable and diligent efforts to assign to Merck any sublicenses previously granted by us.

Manufacturing

We currently do not own nor do we plan to own, facilities for clinical or commercial manufacturing of our sole product candidate, LUM-201. For our OraGrowtH Trials, we relied on an existing supply of the LUM-201 active pharmaceutical ingredient ("API") obtained in connection with the Lumos Merck Agreement that was sufficient for such trials. We have successfully manufactured an initial good manufacturing practices ("GMP") batch of API using a new supplier and with this API we were able to successfully manufacture a clinical trial material batch of LUM-201 which we plan to use to begin to prepare for our Phase 3 clinical trial. We intend to use this contract manufacturer to produce additional clinical drug product supply for future clinical trial needs, including a Phase 3 clinical trial, and will continue the process of performing a technology evaluation and optimization with this third party to manufacture additional API to support future clinical trials.

Ebola Vaccine

In November 2014, NewLink entered into the NewLink Merck Agreement with Merck to develop and potentially commercialize its Ebola vaccine rVSVΔG-ZEBOV that it licensed from PHAC. rVSVΔG-ZEBOV was also eligible to receive a PRV if approval was granted by the FDA, with the Company entitled to 60% of the PRV value obtained through sale, transfer or other disposition of the PRV. On December 20, 2019, Merck announced that 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. Pursuant to the asset purchase agreement, Merck agreed, among other things, to pay us for the PRV in two installments. As required by the agreement, Merck paid us $34.0 million on September 1, 2020 and $26.0 million on January 11, 2021.

We have received and have the potential to continue to earn royalties on sales of the vaccine in certain countries. However, we believe that the market for the vaccine will be limited primarily to areas in the developing world that are excluded from royalty payment or where the vaccine is donated or sold at low or no margin and, therefore, we do not expect to receive material royalty payments from Merck in the foreseeable future.

Oncology Candidates

We have three small-molecule product candidates, which we acquired from NewLink in the merger. These product candidates include two indoleamine-2, 3-dioxygenase pathway inhibitors, indoximod and NLG802 (a prodrug of indoximod), and one direct IDO1 enzymatic inhibitor, NLG919.

Two U.S. patents covering both the salt and prodrug formulations of indoximod were issued in the United States on August 15, 2017 and February 19, 2019, respectively, providing exclusivity until at least 2036. We are continuing to pursue international patent coverage for these formulations in some countries. We may explore the potential for further development and licensing opportunities for these product candidates; however, we currently do not have any active program for these acquired small molecule product candidates.

Government Regulations

United States-FDA process

In the United States, the FDA regulates drugs. The Federal Food, Drug, and Cosmetic Act, 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 we may not be able to obtain the required regulatory approvals.

Approval process

FDA approval is required for 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 we must complete before we 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 institutional review boards ("IRBs"), 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 ("GCP") to establish the safety and efficacy of the drug for each indication to the FDA's satisfaction;
- submission to the FDA of a new drug application (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 our 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 our product candidates and/or jeopardize our ability or our collaborators' ability to commence product sales and generate revenue.

Clinical trials

Clinical trials involve administering the IND 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 IND 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. We typically refer 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. We 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, we can prepare and submit an NDA to the FDA, who must approve the NDA before we 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 an NDA, the data we submit 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 we submit 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 our 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 Risk Evaluation Mitigation Strategies ("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 we 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 we can implement it. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we 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. We 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, and 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.

In response to the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), on January 24, 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, 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;
- requirements under the federal Physician Payments Sunshine Act for applicable drug manufacturers to report annually information related to payments and other transfers of value made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals as well as information regarding ownership or investment interests held by physicians and their immediate family members;
- Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their implementing regulations, also imposes obligations, including mandatory contractual terms, on covered entities, which are health plans, healthcare clearinghouses, and certain health care providers, as those terms are defined by HIPAA, and their respective business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- 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; and
- analogous and related 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; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations 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, marketing expenditures, or drug pricing; state and local laws that require the registration of pharmaceutical sales and medical representatives; state laws, such as the California Consumer Privacy Act of 2018 ("CCPA"), the California Privacy Rights Act ("CPRA"), and Washington's My Health, My Data Act, that 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.

The PPACA continues to significantly impact the United States' pharmaceutical industry. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA. In June 2021, the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the PPACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the PPACA. Thus, the PPACA will remain in effect in its current form. It is

possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how future challenges and healthcare measures promulgated by the Biden administration will impact the PPACA, our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the PPACA could be time-intensive and expensive, resulting in a material adverse effect on our business. The PPACA contained provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by 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. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the U.S. Department of Health and Human Services Secretary, or HHS Secretary, as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The PPACA made several changes to the Medicaid Drug Rebate Program, including increasing the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care organizations. The PPACA also established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off 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.

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 2032, unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012 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.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, under the American Rescue Plan Act of 2021, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs has been eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material adverse impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us, and the pharmaceutical industry as a whole, is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

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. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. In addition, the FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida in importing Canadian prescription drugs. Regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state

governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

European Union-European Medicines Agency (the "EMA") process

In the European Union, our product candidates may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if an MA has been issued, 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, 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 ("Clinical Trials Regulation") 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 Clinical Trials Regulation entered into application on January 31, 2022 and is intended to simplify the current rules for clinical trial authorization and standards of performance. For instance, there will be a streamlined application procedure via a single-entry point, a European Union portal and database. The new clinical trial portal and database will be maintained by the EMA in collaboration with the European Commission and the European Union Member States. The objectives of the new Regulation include consistent rules for conducting trials throughout the European Union, consistent data standards and adverse events listing, and consistent information on the authorization status. Additionally, information on the conduct and results of each clinical trial carried out in the European Union will be made publicly available.

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, 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 MA 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 MA 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 European Economic Area, 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 MA can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national MA.

We do not foresee that any of our current product candidates will be suitable for a national MA as they fall within the mandatory criteria for the Centralized Procedure. Therefore, our product candidates will be approved through Centralized Procedure.

Starting in January 2021, the Medicines and Healthcare products Regulatory Agency ("MHRA") took on additional regulatory responsibilities for medical products marketed in the UK, as pan-EU regulatory procedures before the EMA will no longer apply in the UK. MHRA recently issued new guidance to the industry regarding regulation under the UK system. Proposals set forth in the new MHRA guidance will take effect through legislative changes that are subject to parliamentary approval, which may increase the amount of resources and time needed for obtaining regulatory approval in the UK and delay our clinical development and commercialization. The full impact of Brexit on our business remains unclear.

Pursuant to Regulation (EC) No 1901/2006, all applications for MA 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 Marketing Authorization Application ("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 may be submitted at any stage of development of the drug but must be submitted 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 we or our partners commercialize drugs, we 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 our or our 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 us, including the suspension of our manufacturing operations or the withdrawal of our 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 an MA is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic MA 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 MAA, 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 MAs 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 us to maintain price levels sufficient to realize an appropriate return on our 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, we may need to conduct expensive pharmacoeconomic trials to demonstrate the medical necessity and cost-effectiveness of our 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 our 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 we receive 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 CMS, 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, our clinical research programs, proposed sales and marketing and education activities, and financial and business relationships with future prescribers of our 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 our 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 we 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 we do not comply with applicable FDA requirements we 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 our 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. Our activities relating to the sales and marketing of our 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, 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), certain non-physician healthcare professionals (including physician assistants and nurse practitioners, among others) and teaching hospitals, as well as other information regarding ownership and investment interests held by the physicians described above and their immediate family members.

In addition, we 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 our 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.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, including the conduct of independent contractors or third parties who act or perform services for or on our behalf, and any sales and marketing activities after a product candidate has been approved for marketing, could be subject to legal challenge and enforcement actions. If our operations are found to be in violation of any of

the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal, and/or administrative penalties and adverse actions, any of which could adversely affect our ability to operate our business and our results of operations. 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 us or our executive officers of violating these laws, our 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 our drugs, if our potential international distribution partners engage in inappropriate activity it can have adverse implications for us.

Facilities

Our corporate headquarters are in Austin, Texas, where we lease approximately 5,000 square feet of office space under a lease expiring in November 2025. We also lease approximately 4,200 square feet of additional executive and administrative office space in Ames, Iowa under a lease that expires in March 2026. We believe we have convenient access to additional space on reasonable terms for our future needs.

Employees and Human Capital

As of December 31, 2023 we had 33 employees. None of our employees are represented by any collective bargaining agreements. We believe that we maintain good relations with our employees.

We are committed to attracting and retaining the best possible talent. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our Company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Available Information

We file annual, quarterly and current reports, proxy statements and other information with the SEC, and we have an Internet website address at www.lumos-pharma.com. We make available free of charge on our Internet website address our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Sections 13(a) or 15(d) of the Exchange Act, as well as our proxy statements as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. You may also obtain copies of such documents from the SEC's website at http://www.sec.gov.

Item 1A. RISK FACTORS

SUMMARY OF RISK FACTORS

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report and our other filings with the SEC before making an investment decision regarding our common stock.

Risks Related to our Financial Condition and Capital Requirements

- We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial and increasing losses for the foreseeable future. We have only one product candidate and no commercial sales, which, together with our limited operating history, makes it difficult to evaluate our business and assess our future viability.
- We currently have no source of product revenue and may never become profitable.
- We will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates and technologies.
- We might not be able to continue as a going concern.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.
- Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code").

Risks Related to the Development and Commercialization of our Product Candidate

- Data from our clinical trials may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- As an organization, we have never conducted a Phase 3 clinical trial or submitted a New Drug Application (an "NDA") before, and may be unsuccessful in doing so for LUM-201. We will need to raise substantial additional capital to fund our Phase 3 trial.
- Our success depends heavily on the successful development, regulatory approval and commercialization of our only product candidate, LUM-201.
- The analysis that supports our 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 our LUM-201 clinical trial design and our future development plans.
- 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.
- If we make changes to our product candidate, additional clinical trials may be required resulting in additional costs and delays.
- 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.

Risks Related to the Operation of our Business

- Our future success depends on our ability to retain our chief executive officer, president and other key members of our management team and to attract, retain and motivate qualified personnel.
- We expect to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- Business disruptions could seriously harm our clinical trials, future revenue and financial condition and increase our costs and expenses.
- If we obtain approval to commercialize LUM-201 outside the United States, we will be subject to additional risks.
- Our internal computer systems, or those of our contract research organizations ("CROs") or other contractors or consultants, may fail or suffer security breaches or incidents, which could result in a material disruption of our drug development programs.

Risks Related to our Intellectual Property

- Our ability to successfully commercialize our technology and products may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad.
- We do not have composition of matter patent protection with respect to LUM-201.
- We may become involved in legal proceedings to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.
- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.
- If we are unable to protect the confidentiality of its trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position.

Risks Related to Government Regulation

- The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of our product candidates.
- Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.
- Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.
- Healthcare reform measures could hinder or prevent our product candidates' commercial success.
- Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our 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 us 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 we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Risks Related to Ownership of Our Common Stock

- The trading price of our common stock has been highly volatile, and could decline significantly.
- The holdings of our stockholders may be substantially diluted, and the prices of our securities may decrease, by future issuances of securities by us.
- 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.
- Our amended and restated bylaws ("Bylaws") designate the state courts in the State of Delaware or, 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.
- We do not anticipate that we will pay any cash dividends in the foreseeable future.
- Provisions in our certificate of incorporation, our Bylaws 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.

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.

Risks Related to our Financial Condition and Capital Requirements

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We do not have any products approved for sale, and we are currently focused on developing our product candidate, LUM-201. Evaluating our performance, viability or future success will be more difficult than if we had a longer operating history or approved products on the market. We continue to incur significant research and development and general and administrative expenses related to our 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. We have incurred significant operating losses in each year since our inception and expect to incur substantial and increasing losses for the foreseeable future. As of December 31, 2023, we had an accumulated deficit of $161.5 million.

To date, we have devoted substantially all of our efforts to research and development, including clinical trials, but have not completed development of any product candidate. We anticipate that our expenses will increase substantially as we:

- continue the research and development of our product candidate, LUM-201, and any future product candidates;
- pursue clinical trials of LUM-201, including our planned Phase 3 clinical trial;
- seek to in-license additional product candidates and incur any future costs to develop these product candidates;
- seek regulatory approvals for LUM-201 and any future product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize LUM-201 or any future product candidates if they obtain regulatory approval, including process improvements in order to manufacture LUM-201 or any future product candidates at commercial scale; and
- enhance operational, financial and information management systems and hire 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, we must succeed in developing and eventually commercializing LUM-201 as well as other products with significant market potential. This will require us 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 we may obtain regulatory approval. We are only in the preliminary stages of some of these activities. We may not succeed in these activities and may never generate revenue that is sufficient to be profitable in the future. Even if we are profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress our value and could impair our ability to raise capital, expand our business, diversify our product candidates, market our product candidates, if approved, or continue our operations.

We currently have no source of product revenue and may never become profitable.

To date, we have not generated any revenues from commercial product sales. Even if we are able to successfully achieve regulatory approval for LUM-201 or any future product candidates, we do not know when any of these products will generate revenue from product sales. Our ability to generate revenue from product sales and achieve profitability will depend upon our

ability, alone or with any future collaborators, to successfully commercialize products, including LUM-201 or any product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenue from product sales from LUM-201 or any future product candidates also depends on a number of additional factors, including our or any future collaborators' ability to:

- complete development activities, including our planned Phase 3 clinical trial of LUM-201, successfully and on a timely basis;
- demonstrate the safety and efficacy of LUM-201 to the satisfaction of 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 our 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 we obtain marketing approval in markets where we intend to commercialize independently;
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- achieve market acceptance of our approved products, if any;
- establish, maintain and protect our 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, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide to or are required by the FDA or foreign regulatory authorities to perform studies or trials in addition to those that we currently anticipate. Even if we are able to complete the development and regulatory process for LUM-201 or any future product candidates, we anticipate incurring significant costs associated with commercializing these products.

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

We will need to raise substantial additional funds over the next few months to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs, including our LUM-201 Phase 3 Trial, and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause substantial dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our 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. Our future financing requirements will depend on many factors, some of which are beyond our control, including the following:

- the rate of progress and cost of our clinical trials, including our planned Phase 3 clinical trial for LUM-201;
- 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 us 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;
- our 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.

We do not have any material committed external source of funds or other support for our planned development efforts. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect 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 us when we need it or such additional financing may not be available on favorable terms. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to LUM-201 or any potential future product candidates, technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be substantially diluted, and the terms of these securities may include liquidation or other preferences that adversely affect its stockholders' rights. For example, in December 2020, we entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as agent (the "Agent"), pursuant to which we may offer and sell from time to time through the Agent up to $50.0 million of shares of our common stock from time to time in "at-the-market" offerings. During the year ended December 31, 2023, we sold an aggregate of 181,700 shares under the Sales Agreement, for proceeds of approximately $0.7 million. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend our planned Phase 3 clinical trial for LUM-201 or one or more of our other clinical trials or research and development programs or our commercialization efforts.

We might not be able to continue as a going concern.

Our consolidated financial statements as of December 31, 2023 have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements also do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if we are unable to continue as a going concern. As of December 31, 2023, we had approximately $36.1 million of cash, cash equivalents and short-term investments, and an accumulated deficit of approximately $161.5 million. Based on our current cash forecast and dependence on our ability to obtain additional financing to fund our operations in advancing our PGHD program into a Phase 3 trial, we concluded that our available cash, cash equivalents and short-term investments as of December 31, 2023 may not be sufficient to fund our operations for at least 12 months from the filing date of this Annual Report, and thus substantial doubt exists as to our ability to continue as a going concern. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

Our plan is to raise additional equity or financing to fund our future operations. While we are seeking additional financing and evaluating financing alternatives to meet our cash requirements for the next 12 months, there can be no assurances that, in the event that we require additional financing, such financing will be available on terms that are favorable to us, or at all. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current stockholders may experience substantial dilution. If we are unable to raise additional funding to meet our working capital needs in the future, then we may be forced to delay or reduce the scope of our research programs and/or limit or cease our operations.

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

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties. Accordingly, our 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 our operating results from one period to the next. In addition, we estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our 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;
- our 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 our agreements with manufacturers;
- expenditures that we 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 our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of LUM-201 or any of our 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 our products candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- competition from existing and potential future drugs that compete with LUM-201 or any of our future product candidates;
- our ability to commercialize LUM-201 or any future product candidate inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

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

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 through March 18, 2020, as a result of the Merger, both historical NewLink and Private Lumos experienced Section 382 ownership changes on March 18, 2020.

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.

Based on subsequent analyses, we did not experience a Section 382 ownership change from March 19, 2020 through December 31, 2022. 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.

Accounting principles generally accepted in the U.S. ("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.

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 Nasdaq. 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, 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. There can be no assurance that remediation of any material weaknesses or significant deficiencies that may be identified would be completed in a timely manner or that the remedial measures will prevent other significant deficiencies or material weaknesses. If we are unable to remediate any significant deficiencies or material weaknesses in internal control over financial reporting, then our ability to analyze, record and report financial information free of material misstatements, to prepare financial statements within the time periods specified by the rules and forms of the SEC and otherwise to comply with the requirements of Section 404 of the Sarbanes-Oxley Act could be negatively impacted. As a result, we may experience negative impacts to our business financial condition or operating results, which would restrict our ability to access the capital markets, require the expenditure of significant resources to correct the weaknesses or deficiencies, subject us to fines, penalties, investigations, or judgments, harm our reputation, or otherwise cause a decline in trading price of our stock and investor confidence in the reliability of our financial statements.

Changes in our effective income tax rate could adversely affect our results of operations in the future.

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 stock-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. For example, the current administration has proposed tax reform legislation to increase the U.S. corporate income tax rate, increase U.S. taxation of international business operations and impose a global minimum tax, which could result in increased marginal corporate tax rates. A number of countries, as well as organizations such as the Organization for Economic Cooperation and Development, support the global minimum tax initiative. Such countries and organizations are also actively considering changes to existing tax laws or have proposed or enacted new laws that could increase our tax obligations in countries where we do business or cause us to change the way we operate our business. 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.

Risks Related to the Development and Commercialization of our Product Candidate

Data from our clinical trials may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

We have published data from our clinical trials and from time to time in the future we expect to publish other data from clinical trials, including our OraGrowthH Trials. Such data from our clinical trials, including our topline results of our OraGrowthH Trials which were released in November 2023, are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available. Data from clinical trials may not be indicative of the final results of the trial or may be inconclusive and are subject to the risk that one or more of the clinical outcomes may materially change as more patient data becomes available. Thus, favorable topline results, like those released in November 2023 related to our OraGrowthH210 and OraGrowthH212 Trials, may not necessarily lead to favorable final results or FDA or other regulatory approval. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically more extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. Similarly, even if we are able to complete our planned and ongoing preclinical studies and clinical trials of our product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other regulatory approval.

As an organization, we have never conducted a Phase 3 clinical trial or submitted a New Drug Application (an "NDA") before, and may be unsuccessful in doing so for LUM-201. We will need to raise substantial additional capital to fund our Phase 3 trial.

We initiated our OraGrowthH210 Trial in the fourth quarter of 2020, and based on the successful results of our OraGrowthH210 Trial, which we announced on November 7, 2023, we intend 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 and will require us to raise substantial additional capital to fund such trial. As an organization, we have never conducted a Phase 3 clinical trial, have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted an NDA before. We also have had limited interactions with the FDA and have not discussed any proposed Phase 3 clinical trial designs or implementations with the FDA. We have not raised significant amounts of equity or debt capital since the Merger was completed in March 2020. Even if the OraGrowthH210 Trial is successful, we may be unable to successfully and efficiently fund, execute and complete necessary clinical trials in a way that leads to an NDA submission and approval of LUM-201. Failure to fund, commence or complete, or delays in, our planned clinical trials would prevent us from or delay us in commercializing LUM-201.

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

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

We 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 we commercialize LUM-201 or any future product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. The FDA approval 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 any future product candidates, we 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. We are pursuing the same regulatory pathway for LUM-201 followed by most of the approved rhGH products and long-acting GH products under development with LUM-201 focused on a subset of previously diagnosed PGHD patients. We intend to study treatment naïve patients by conducting trials including our OraGrowtH210 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 we 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 we observe for LUM-201 in the OraGrowtH210 Trial do not correlate to 12 month mean height velocities that we ultimately observe in any Phase 3 clinical trial that we 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 we 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 our 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 we are unable to obtain regulatory approval for LUM-201 in one or more jurisdictions, or any approval contains significant limitations, we 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 any future product candidates, once obtained, may be withdrawn. Furthermore, even if we obtain regulatory approval for LUM-201, the commercial success of LUM-201 will depend on a number of factors, including the following:

- development of our 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 our third-party manufacturers to manufacture quantities of LUM-201 using commercially viable processes at a scale sufficient to meet anticipated demand and reduce our cost of manufacturing, and that are compliant with the FDA's cGMP;
- our 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 our own or our 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 our obligations in our intellectual property licenses with third parties upon favorable terms.

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

The analysis that supports our 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 our LUM-201 clinical trial design and our future development plans.

The probability of the OraGrowthH210 Trial succeeding is highly dependent on the adequacy of the trial design. In designing such trial, we reviewed data and analysis from three studies on LUM-201 completed by Merck in the 1990s (the "Merck Trials") and we incorporated the results of our analysis of Merck's clinical data into the design of the OraGrowthH210 Trial. However, we could have misinterpreted or performed a flawed analysis of such data. Factors that could have affected our 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 our ability to effectively predict how changes to trial design might affect the OraGrowthH210 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 some of the source documentation for the Merck Trials, may not have been made available to us and so could not be referenced for our analysis and OraGrowthH210 Trial design; and
- bias in small sample size and other limitations inherent in the post-hoc analysis of the Merck Trials upon which we have relied for our OraGrowthH210 Trial design 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 OraGrowthH210 Trial that could cause it to fail, which would materially adversely impact our business, future development plans, and prospects.

Because the results of preclinical testing or earlier clinical trials are not necessarily predictive of future results and may not translate to other indications, 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. We do not know whether the clinical trials we are conducting, or may conduct, will demonstrate adequate efficacy and safety to result in regulatory approval to market LUM-201. Even if we believe that we have adequate data to support an application for regulatory approval to market our product candidates, the FDA, the EMA, or other applicable foreign regulatory authorities may not agree and may require that we conduct additional clinical trials. If later-stage clinical trials do not produce favorable results, our 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 OraGrowthH210 Trial compared to the previously conducted Merck Trials or in our planned Phase 3 clinical trial. Trials in additional indications may not be successful or may exhibit new or increased safety risks. While the topline Phase 2 results of our OraGrowthH210 Trial were encouraging, there was an imbalance in the baseline characteristics of the control arm and our final results may be materially different. 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, while we are planning to move forward with the 1.6 mg/kg/day dose of LUM-201 based on the topline Phase 2 data that we released on November 7, 2023, this may not be the optimal dose for LUM-201 and we may incur additional costs or delays if we subsequently conclude there is a more optimal dose or if the FDA requires us to perform additional analysis regarding the optimal dose. Even if an optimal dose is established in one indication, different doses may be optimal in other indications requiring additional clinical trials to determine such optimal dosing.

If we make changes to our product candidate, 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 our product candidate through modifications to its formulation or chemical composition. This research program is part of a broader technology transfer program to establish manufacturing capacity to support our future clinical efforts. Under this technology transfer program, while the process is unlikely to produce identical results, we are working to ensure that the resultant product is equal to or better than the product made or acquired by our licensor. 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 our 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. Material changes to product candidates, including changes in the methods of manufacturing, carry the risk that they will not achieve consistent purity, identity, quality, efficacy and results. Any of these changes could cause our product candidate to perform differently and could affect planned or other clinical trials conducted with product candidates produced using the modified manufacturing methods, materials, and processes. This could delay completion of clinical trials and could require non-clinical or clinical bridging and comparability studies, which could increase costs, delay approval of our product candidate and jeopardize our ability to commercialize our product candidate, if approved. 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 our 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.

Public health crises, including pandemics or similar outbreaks, such as COVID-19, have, and could in the future, adversely impact our business, including our non-clinical studies and planned clinical trials.

Public health crises such as pandemics or similar outbreaks, such as COVID-19, have and could continue to adversely impact our business.

As a result of public health crises, such as the COVID-19 outbreak, or similar pandemics, we have experienced, and may continue to experience disruptions that could severely impact our business, manufacturing, preclinical development activities, preclinical studies and planned clinical trials, including:

- delays or difficulties in enrolling patients in clinical trials;
- government shutdowns, interruption or delays in the operations of the U.S. Food and Drug Administration, other agencies and comparable foreign regulatory agencies, which may impact timelines for regulatory submission, trial initiation and regulatory approval;
- interruption or delays in our CROs and collaborators meeting expected deadlines or complying with regulatory requirements related to preclinical development activities, preclinical studies and planned clinical trials;
- interruptions of, or delays in receiving materials, such as LUM-201 and recombinant human growth hormone, for our clinical trial, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;

- delays or difficulties in any planned clinical site initiation, including difficulties in obtaining IRB approvals, recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from any planned clinical trials following enrollment as a result of contracting an infectious disease or being forced to quarantine;
- diversion of healthcare resources away from the conduct of our preclinical development activities, preclinical studies and planned clinical trials, including the diversion of hospitals serving as any potential clinical trial sites and hospital staff supporting the conduct of our planned clinical trials;
- interruption of planned key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and planned clinical study endpoints;
- limitations on employee or collaborator resources that would otherwise be focused on the conduct of our preclinical development activities, preclinical studies and planned clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions;
- reduced ability to engage with the medical and investor communities due to the cancellation of conferences scheduled throughout the year; and
- changes in clinical site procedures and requirements as well as regulatory requirements for conducting clinical trials during a public health crisis.

The extent to which a public health crisis may impact our business, preclinical studies and clinical trials will depend on many factors, which are highly uncertain and cannot be predicted with confidence, such as the duration of the crisis, travel restrictions and actions to contain the crisis or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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, we may incur additional costs, experience delays in completing or ultimately fail in completing the development and commercialization of LUM-201 or our future product candidates.

Before obtaining regulatory approval for the sale of any product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our 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 our clinical trials could occur at any stage of testing.

We have identified several aspects of the OraGrowthH210 Trial protocols that could potentially delay or prevent our ability to receive regulatory approval or commercialize LUM-201. For example, we may be administering LUM-201 at dose levels that are not as efficacious and/or safe as other rhGH therapies. The OraGrowthH210 Trial will test doses of LUM-201 that are equal to, and two and four times higher than, the highest doses tested in the pediatric 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, frequent safety assessments may be required during the trial.

FDA or other regulatory authorities may disagree with our clinical trials protocol or study design and may require us to change our clinical studies protocol or laboratory procedures used to identify patients that meet the entry criteria for our studies, which could negatively impact our existing arrangements with clinical laboratories or vendors engaged for our clinical trials, delay enrollment, or cause us to modify our studies protocol, all of which could delay our clinical development plans and increase the amount of time and expense required for regulatory approval of LUM-201, if any, or negatively impact the scope of our proposed indication or target patient population. For example, in July 2021, the FDA requested an extension of the OraGrowthH210 Trial from six months to 12 months and restricted treatment with LUM-201 to no more than 12 months until additional efficacy data was available for review. After review of the preliminary safety and efficacy data from our OraGrowthH210 and OraGrowthH212 Trials, the FDA lifted the partial clinical hold and now permits treatment with LUM-201 beyond 12 months. As a result, the OraGrowthH210 Trial was extended to up to 24 months and our OraGrowthH212 Trial was extended to treat subjects until near adult height. The extension of these treatment periods will increase the amount of time and

expense required for these trials. In addition to trials design factors, we may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our 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 we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials may be larger than we anticipate, enrollment of subjects who meet our inclusion criteria in these clinical trials may be insufficient or slower than we anticipate, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our existing supply of the LUM-201 API was manufactured more than 20 years ago and, while we have conducted testing and believe this supply is suitable for clinical use, it may unexpectedly become unusable or documentation concerning this supply may be in the possession of third parties and become unavailable over time;
- the cost of clinical trials or the manufacturing of our product candidates may be greater than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that our 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 our proposed clinical development plans, including our clinical trial design or protocol;
- we have been, and may in the future be required to modify our clinical trial protocol or design, and thus our arrangements with clinical trial vendors or trial sites, based on regulators' feedback;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of LUM-201 or any future product candidates beyond those that we contemplate, if we are 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, we 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.

Our product development costs will also increase if we experience delays in testing or approvals. We do 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 we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to commercialize our product candidates and harm our business and results of operations.

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

Even if we receive 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, we believe that the treatment will only be effective for approximately 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 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 our ability to generate revenue.

LUM-201 or our 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.

Our 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 us 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 our knowledge, no serious drug-related adverse events have been reported in children treated with LUM-201 in our OraGrowtH Trials or otherwise. However, we 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, our 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 we may experience in its clinical trials in the future, we may not receive approval to market LUM-201 or any future product candidates, which could prevent us from ever generating revenue or achieving profitability. Results of our trials could reveal an unacceptably high severity or prevalence of adverse events. In such an event, our 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 our business, results of operations, financial condition, cash flows and future prospects.

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

- we may be forced to suspend the marketing of such product;
- regulatory authorities may withdraw our 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 REMS, or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;

- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

Even if our 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 our business, financial condition, results of operations and growth prospects.

Assuming the success of our clinical trials, we anticipate seeking regulatory approval for LUM-201 in all major jurisdictions for treatment of a subset of PGHD patients based on a once daily weight-based dosing regimen. It is possible though that the FDA, the EMA, or regulatory agencies in other countries may not consider the results of our 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 though we achieved favorable results in the OraGrowtH210 Trial or if we achieve favorable results in our planned Phase 3 clinical trial, considering that LUM-201 is a new chemical entity the FDA may nonetheless require that we 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 we fail to obtain FDA or other regulatory approval of LUM-201 or if the approval is narrower than what we seek, it could have a material adverse effect on our 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 our 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, we may not generate significant product revenue and we may not become profitable on a sustained basis or at all.

In August 2021, the FDA approved a competitive treatment, the once-weekly injectable, Skytrofa, for the treatment of patients with PGHD, and other companies, including large worldwide pharmaceutical companies, are also currently developing products that provide weekly injection-based treatment for PGHD. In particular, in 2023, the FDA approved two new once-weekly injection products, Ngenla and Sogroya, that would reduce the number of injections over the course of treatment for a patient. With the approval of once-weekly injections, physicians, patients and their families may prefer a once weekly treatment option over LUM-201's daily treatment if it is available to them.

LUM-201 has never been manufactured on a commercial scale, and there are risks associated with manufacturing additional supply and scaling up manufacturing to commercial scale. We have arranged 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.

We have an existing supply of the LUM-201 API obtained in connection with the APA by and between Lumos and Ammonett and the Lumos Merck Agreement entered into in November 2014 with Merck and such supply was sufficient for our OraGrowthH210 Trial. However, we will need additional supply of LUM-201 to conduct our planned Phase 3 trial. The LUM-201 API has never been manufactured by a manufacturing site other than Merck on a commercial scale, and there are risks associated with manufacturing additional supply of LUM-201 for clinical trials and scaling up of the manufacturing process to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, supply chain disruptions and timely availability of raw materials. Even if we could otherwise obtain regulatory approval for LUM-201, there is no assurance that the manufacturer we have arranged will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities for our clinical trials or to meet the requirements for the potential launch of the product or to meet potential future demand. If the manufacturer is unable to begin production in a timely and efficient manner or produce sufficient quantities of the approved product for our clinical trials or commercialization, our clinical and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our failure to successfully identify, acquire, develop and commercialize additional products or product candidates could impair our ability to grow.

Although a substantial amount of our efforts will focus on the continued clinical testing and potential approval of our product candidate, LUM-201, a key element of our 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 our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our 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 us for the license or acquisition of product candidates and approved products. We have 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, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Any product candidate that we acquire 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, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured profitably or achieve market acceptance.

We currently have no sales or distribution personnel and only limited marketing capabilities. If we are unable to develop a sales and marketing and distribution capability on our own or through collaborations or other marketing partners, we will not be successful in commercializing LUM-201 or other future products.

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

There are risks involved with both establishing our 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. Recent labor market dynamics have resulted in fewer candidates available to fill employment openings and us having to offer higher wages. As such, recruiting and retaining employees has become more difficult and, in some cases, we may not be able to obtain suitable candidates on acceptable terms to fill open positions. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We also may not be successful entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We 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 our products effectively and could damage our reputation. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new therapeutic products is highly competitive. We face competition with respect to LUM-201 and will face competition with respect to any product candidates that we 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 our 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 we 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 our target indications.

We are developing our 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 rhGH therapies administered by daily subcutaneous injection and used for the treatment of GHD, principally Norditropin® (Novo Nordisk A/S (“Novo Nordisk”)), Humatrope® (Eli Lilly and Company), 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.), as well as therapies administered by weekly subcutaneous injection by Skytrofa® (Ascendis Pharma), Ngenla® (OPKO Health, Inc. in collaboration with Pfizer Inc.) and Sogroya® (Novo Nordisk, Inc.). These rhGH drugs, apart from Valtropin, Skytrofa, Ngenla and Sogroya, 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 Novo Nordisk, Genexine Inc. and OPKO Health, Inc. (in collaboration with Pfizer). During the fourth quarter of 2021, OPKO Health, Inc.'s NGENLA® (somatrogon), a once-weekly injectable long-acting human growth hormone molecule, was granted regulatory approvals in Europe, Japan, Australia and Canada and became commercially available in Canada during the first quarter of 2022.

Many of our competitors, including a number of large pharmaceutical companies that compete directly with us, 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 we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our 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 us 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, our programs.

A key part of our strategy is to evaluate and enter into strategic alliances in the future, and we may not be able to successfully identify or execute on such alliances on terms favorable to us.

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

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

As part of our strategy, we plan to evaluate and enter into collaboration agreements with third parties with respect to LUM-201 for the commercialization of this product candidate in or outside the United States, or with respect to future product candidates for commercialization in or outside the United States. Our 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. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates, and limited control over certain intellectual property rights related to the collaboration as well as other elements of the collaboration we would be relying on our collaborators for. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements or on our ability to achieve any milestones specified in such arrangements. Any termination or disruption of collaborations could result in delays in the development of product candidates, increase our costs to develop the product candidates or the termination of development of a product candidate.

If we are 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 our 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, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our 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. We cannot be sure that reimbursement will be available for any product that we commercialize 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 we obtain marketing approval. Obtaining reimbursement for our 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, we may not be able to successfully commercialize any product candidate that we successfully develop.

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 our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our 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. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our 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, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. Our business could be materially harmed if reimbursement of our approved products, if any, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels.

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

We face 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 we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our 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 we may develop.

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

We have 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 our settlement agreement with The Avicena Group, Inc. and its Chief Executive Officer, we have 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 through November 19, 2037. As a result, we may be limited in our ability to develop or collaborate on products in those fields, and we could miss valuable future opportunities thus potentially adversely affecting our financial results, business and business prospects.

Under the worldwide license and collaboration agreement between NewLink and Merck, dated November 2014 (the "NewLink Merck Agreement"), future royalty obligations may exceed any future limited revenues, if any, from any future sales of ERVEBO®.

Even now that ERVEBO® has been approved and we have received limited revenues from sales of ERVEBO®, a number of factors may adversely affect commercial sales of such product and any future revenues under the NewLink Merck

Agreement. For example, lack of familiarity with the viral vaccine and potential adverse events associated with vaccination may adversely affect physician and patient perception and uptake of such 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. Finally, in certain cases, our obligations to pay royalties to the Public Health Agency of Canada ("PHAC") may exceed the royalties we receive from Merck.

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. Our Ebola vaccine product candidate was studied in clinical trials in West Africa. Additionally, we have agreed to supply NLG919 and NLG802 for future investigator-initiated clinical trials. We are also in a clinical collaboration with Massachusetts General Hospital to evaluate oral LUM-201 in nonalcoholic fatty liver disease. 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.

Our business may be adversely impacted by the consequences of military conflicts.

Economic, political and social conditions, including supply chain disruptions, inflation, and clinical site closures, resulting from military conflicts, including Russia's invasion of Ukraine and the conflicts in the Middle East, could materially disrupt our clinical trials, increase our costs and may disrupt planned clinical development activities. For example, we rely on suppliers in Germany, and to the extent the military conflict between Ukraine and Russia adversely impacts the ability of our suppliers to produce and distribute the supplies we need for our OraGrowtH210 Trial, or such distribution cannot be done on a timely basis, the timing for completing our OraGrowtH210 Trial may be adversely impacted. In addition, the United States, United Kingdom and European Union governments, among others, have instituted various sanctions and export-control measures in response to the invasion, including comprehensive financial sanctions, targeted at Russia or designated individuals and entities with business interests and/or government connections to Russia or those involved in Russian military activities. Governments have also enhanced export controls and trade sanctions targeting Russia's imports of goods. The duration and intensity of this conflict and its economic impact on our European operations is uncertain at this time, but it is possible that our business, results of operations and financial condition could be materially and adversely affected.

Risks Related to the Operation of our Business

Our future success depends on our ability to retain our chief executive officer, president and other key members of our management team and to attract, retain and motivate qualified personnel.

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

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We 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. Recent labor market dynamics have resulted in fewer candidates available to fill employment openings and us having to offer higher wages. As such, recruiting and retaining employees has become more difficult and, in some cases, we may not be able to obtain suitable candidates on acceptable terms to fill open positions. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating its research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We expect to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2023, we had 33 employees. As we plan and undertake our Phase 3 clinical trial following the favorable data read-out of our OraGrowtH210 Trial which we announced on November 7, 2023, subject to obtaining required additional funding, we expect to experience significant growth in the number of our employees and the scope of our operations,

particularly in the areas of drug development, regulatory affairs, commercial development and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively, which we anticipate being conducted at numerous clinical sites;
- identification, recruitment, and the integration of additional employees we may require with the expertise and experience to support our future growth;
- management of our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- managing any future additional relationships with various strategic partners, suppliers and other third parties; and
- improving our managerial, development, operational and finance reporting systems and procedures.

Our failure to accomplish any of these tasks could prevent us from successfully growing. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Business disruptions could seriously harm our clinical trials, future revenue and financial condition and increase our costs and expenses.

Our operations or those of our vendors or clinical trials, could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, production shortages, supply chain disruptions and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

If we obtain approval to commercialize LUM-201 outside the United States, we will be subject to additional risks.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our 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 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.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches or incidents, which could result in a material disruption of our drug development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage, interruptions of service and other disruptions from computer viruses,

unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not, to our knowledge, experienced any material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. Additionally, any disruption or security breach or incident resulting in any loss, destruction, unavailability, or unauthorized alteration, disclosure, dissemination, or processing of, or damage or unauthorized access to, our systems, any data processed or maintained on our behalf, or other assets, or for it to be believed or reported that any of these occurred, could cause us to incur liability, financial harm and reputational damage and the development and commercialization of our product candidates could be delayed. We cannot assure you that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, contractors, consultants or other third parties, will prevent significant breakdowns, disruptions, or breaches in systems or have prevented or will prevent other cyber incidents that cause loss, destruction, unavailability, alteration or dissemination of, or damage or unauthorized access to, our data or other data processed or maintained on our behalf or other assets that could have a material adverse effect upon our reputation, business, operations or financial condition.

Our business and operations would suffer in the event of system failures, cyber-attacks, and security breaches or incidents.

Our computer systems, as well as those of various third parties on which we will rely, including CROs and other contractors, consultants, and law and accounting firms, may sustain damage or otherwise be disrupted by or from computer viruses, ransomware and other malicious code, unauthorized access, security breaches and incidents, phishing attacks and other forms of social engineering attacks, cybercriminals, natural disasters, terrorism, war and telecommunication and electrical failures. 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, and may be heightened by geopolitical events such as the war between Russia and Ukraine and conflicts in the Middle East. Many of our employees have been working and continue to work remotely, which may increase certain cybersecurity risks. We may in the future experience material system failures, security breaches or incidents that could cause interruptions in our operations or result in a material disruption of our drug development programs.

For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss, corruption or unavailability of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our information technology systems or security breaches or incidents, suffered by us, or any of our third-party CROs, other contractors, consultants, supply or manufacturing partners or other third parties on which we rely, could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure, dissemination, or other processing of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event or any other security breach or incident that leads to the loss, corruption, or unavailability of, damage to, unauthorized access to, or use, alteration, disclosure, dissemination, or other processing of, personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, result in governmental inquiries, demands, investigations or other proceedings, and claims, demands, and litigation by governmental authorities or private groups or individuals, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Regardless of our security measures and contractual protections, any actual or perceived security breach or incident or breach of our contractual obligations could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach or incident.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in or, failure or security breach or incident of our systems or third-party systems where information important to our business operations or commercial development is stored or otherwise processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Our employees, independent contractors and consultants, principal investigators, CROs, 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 us and harm our reputation.

We are exposed to the risk that our employees, independent contractors and consultants, principal investigators, CROs, contract marketing organizations ("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 our manufacturing standards or those required by cGMP, 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 our employees and other 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 our reputation. We have implemented a code of business ethics and conduct, but it is not always possible to identify and deter such misconduct, and the precautions we take 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 us 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 us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. For example, if one of our manufacturing partners was placed under a consent decree, we may be hampered in our ability to manufacture clinical or commercial supplies.

If we fail to fulfill our obligations under our contractual commitments, our counterparties could terminate the applicable agreements or make claims against us, which could have a materially adverse effect on us.

Under our license agreement with Merck and its APA with Ammonett, we are obligated to use commercially reasonable and diligent efforts to develop and commercialize LUM-201. We are also obligated to make substantial milestone payments and royalties to both Merck and Ammonett, which may limit our future profitability and our ability to enter into marketing partnership agreements. If we fail to fulfill our obligations under our 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, or make claims against us under both agreements, which could have a materially adverse effect on our business, results of operations and prospects.

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

We do not independently conduct clinical trials. We rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as 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 our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

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

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

We currently have limited experience in, and we do not own facilities for, clinical-scale manufacturing of our sole product candidate, LUM-201. We relied upon an existing supply of LUM-201 API obtained in connection with the APA by and between Lumos and Ammonett and the Lumos Merck Agreement and such supply was sufficient for our OraGrowthH210 Trial. In preparation and anticipation of our Phase 3 clinical trial, we have manufactured a small batch of API and LUM-201 drug product. However, we have not completed a scale up manufacturing of LUM-201 and will need additional supply of LUM-201 to conduct our Phase 3 trial. We currently intend to rely upon a single third-party CMO to manufacture and supply drug product for our 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 production shortages resulting from events affecting raw material supply or manufacturing capabilities, difficulties with production costs, yields, and 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 us were to encounter any of these difficulties or otherwise fail to comply with its obligations to us or under applicable regulations, our ability to provide study drugs in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

All manufacturers of our product candidates must comply with cGMP requirements enforced by the FDA through our facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our 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. We have little control over our 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 our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we 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 our product candidates, entail higher costs or impair our 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 our 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 us.

We plan to explore strategic collaborations that may never materialize or may fail.

As part of our strategy, we plan to explore a variety of possible strategic collaborations in an effort to gain access to additional product candidates, geographical regions, or resources. At the current time, we cannot predict what form such a strategic collaboration might take, if any. 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 NewLink 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;
- 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.

We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

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.

Risks Related to our Intellectual Property

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

Our success depends on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our 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 we rely on are highly uncertain. Pending and future patent applications may not result in patents being issued which protect our 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 we rely on or narrow the scope of our patent protection. The laws of foreign countries may not protect our 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, we cannot be certain that the inventors of the key patents we have or may acquire were the first to make the inventions claimed in our licensed patents or pending patent applications, or that we were 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, and in the United States on or after March 16, 2013, the first to file a patent application is entitled to the patent.

Even if the pending patent applications we rely on issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our 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 we rely on may be challenged in the courts or patent offices in the United States or abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our 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 our 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, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

We do not have composition of matter patent protection with respect to LUM-201.

We own certain patents and patent applications with claims directed to specific methods of using LUM-201 and we 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 ODD for treatment of GHD. However, we do not have composition of matter protection in the United States and elsewhere covering LUM-201. Since we do 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 we do 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, we may be limited in our ability to list our patents in the FDA's Orange Book if the use of our product, consistent with its FDA-approved label, would not fall within the scope of our patent claims. Also, our competitors may be able to offer and sell products so long as these competitors do not infringe any other patents that we (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 our 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 our patents would limit our ability to generate revenue from the sale of LUM-201, if approved for commercial sale.

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

Competitors may infringe or otherwise violate the patents we rely on, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringed their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent we are 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 we are 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 our 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. We or our licensers may become involved in proceedings, including post grant proceedings, oppositions, interferences, derivation proceedings inter partes reviews, patent nullification proceedings, or re-examinations, challenging our 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 our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Our business could be harmed if the prevailing party does not offer us 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 our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, data which form the basis of our 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 we are unable to resolve these disputes, we could lose valuable intellectual property rights.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our 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 our common stock. Such litigation or proceedings could substantially increase our 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 our ability to compete in the marketplace.

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

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

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, and could distract our 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 our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we 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 our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position.

In addition to our products and patented technology, we rely upon confidential proprietary information, including trade secrets, unpatented know-how, technology and other proprietary information, to develop and maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. These agreements are designed to protect our proprietary information; however, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets, or that technology relevant to our 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, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our 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 we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business.

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

Filing, prosecuting and defending our intellectual property rights throughout the world may be prohibitively expensive to us and to our licensors. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop our or their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our products in jurisdictions where we or our licensors do not have any issued patents and our 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 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 could result in substantial cost and divert our efforts and attention from other aspects of our business.

We are dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we would not be able to continue developing our sole product candidate, LUM-201. If we breach the agreement under which we license the use, development and commercialization rights to our sole product candidate or technology from third parties or fail to meet certain development or payment deadlines, we could lose license rights that are important to our business.

In connection with the APA, we were assigned the Lumos Merck Agreement under which we are granted rights to intellectual properties that are important to our business, and we may need to enter into additional license agreements in the future. Our existing license agreement imposes, and we expect 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 we fail to comply with our obligations under the agreement, Merck, the licensor, may have the right to terminate the license, in which event we would not be able to develop or market products, which could be covered by the license. Our 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 we are unable to enter into necessary licenses on acceptable terms.

As we have done previously, we may need to obtain licenses from third parties to advance our research or allow commercialization of sole product candidate, and we 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. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation to pay royalties and/or other forms of compensation.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our 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 our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to development and commercialization of our 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 our licensors, us, and our partners.

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

Our current license for LUM-201 and any future licenses that we 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, we may not be able to adequately influence patent prosecution or prevent inadvertent lapses of coverage due to failure to pay maintenance fees. If we fail to comply with any of our obligations under a current or future license agreement, our licensor(s) may allege that we have breached our license agreement and may accordingly seek to terminate the license. In addition, future licensor(s) may decide to terminate our license at will. Termination of any current or future licenses could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and business prospects.

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

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

- others may be able to make and/or use products that are similar to our product candidates but that are not covered by the claims of the patents that we own;
- inventors of patents that we own 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 ours or our licensors' technologies without infringing our intellectual property rights;
- pending patent applications may not lead to issued patents, including in China, a potentially significant market for LUM-201;
- issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our 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 our or our 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 us and/or our 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, our competitors might be able to use our technologies and those technologies licensed to us and this circumstance would have a material adverse effect on our business.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our 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 our 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 our business and financial condition.

If we are 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 our marketing exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, if any, one or more of the United States patents covering our 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 our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, us or our 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 we request.

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

Risks Related to Government Regulation

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of our 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 we nor our collaboration partners are permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA. Neither we nor our 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 us 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 us;
- restrictions on operations, including costly new manufacturing requirements; and
- seizure or detention of our products or import bans.

Prior to receiving approval to commercialize any of our product candidates in the United States or abroad, we and our 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 we and our collaboration partners believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our product candidates to humans may produce undesirable adverse events, which could interrupt, delay or cause suspension of clinical trials of our product candidates and result in the FDA or other regulatory authorities denying approval of our 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 we could encounter problems that cause us 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 us from 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 our interpretation of data from preclinical studies or clinical trials;
- the FDA might not approve our or our third-party manufacturer's processes or facilities;
- the FDA may disagree with the design, implementation or results of our 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 we seek approval;
- data collected from clinical trials of our drug candidates may not be sufficient to support the submission of an NDA; and
- we may be unable to demonstrate to the FDA a drug candidate's risk-benefit ratio for our 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, our business and results of operations will be materially and adversely harmed.

Further, the FDA's or other ex-U.S. regulators' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If the Supreme Court reverses or curtails the *Chevron* doctrine, which gives deference to regulatory agencies in litigation against FDA and other agencies, more companies may bring lawsuits against FDA to challenge longstanding decisions and policies of FDA, which could undermine FDA's authority, lead to uncertainties in the industry, and disrupt FDA's normal operations, which could delay FDA's review of our marketing applications. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing

approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail 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 we 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, we 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 we are in violation of these restrictions, we 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 our 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 our 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 we 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 us, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we 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 us;
- restrictions on operations, including costly new manufacturing requirements; and
- seizure or detention of our products or import bans.

The regulatory requirements and policies may change and additional government regulations may be enacted with which we may also be required to comply. We 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 we are not able to maintain regulatory compliance, we may not be permitted to market our future products and our business may suffer.

Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.

We intend 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 our future products in regions such as the EEA, Asia Pacific, and many other foreign jurisdictions, we must obtain separate regulatory approvals.

For example, in the EEA, medicinal products can only be commercialized after obtaining 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.

We have 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. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file we may not receive necessary approvals to commercialize our products in any market.

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

In the United States, there have been and we expect 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 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.

There have been legislative and judicial efforts to repeal, replace, or change some or all of the PPACA. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the PPACA, dismissing the case without specifically ruling on the constitutionality of the PPACA. Accordingly, the PPACA remains in effect in its current form. It is unclear how future litigation and healthcare measures promulgated by the Biden administration will impact the implementation of the PPACA, our business, financial condition and results of operations. Litigation and legislation over the PPACA may continue, with unpredictable and uncertain results. Complying with any new legislation or reversing changes implemented under the PPACA could be time-intensive and expensive, resulting in a material adverse effect on our business. We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our 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, including aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, starting in 2013, which will remain in effect through 2032, unless additional Congressional action is taken. In January 2013, President Obama signed into law 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. We 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. For example, in January 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace, which also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. Under the American Rescue Plan Act of 2021, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs has been eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material adverse impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear and could have a material adverse effect on our business, financial condition, and results of operations. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

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. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. Additionally, FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida.

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. We 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:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, 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. 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.

Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our 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 us 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 we fail to comply with healthcare regulations, we could face substantial penalties and our 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 we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain 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 ours 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, in part, applicable manufacturers of drugs, devices, biologics and medical supplies, for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, to report annually to the CMS information related to certain payments and other transfers of value made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- 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 HITECH 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 and related 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, use, and other processing of health data relating to individuals 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 our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union. The United Kingdom has implemented legislation similar to the GDPR, including the UK Data Protection Act and legislation similar to the GDPR referred to as the UK GDPR, which provides for fines of up to the greater of 17.5 million British Pounds or 4% of a company's worldwide turnover, whichever is higher. We cannot fully predict how the Data Protection Act, the UK GDPR, and other United Kingdom data protection laws or regulations may develop in the medium to longer term nor the effects of divergent laws and guidance regarding how data transfers to and from the United Kingdom will be regulated. We may find it necessary or otherwise appropriate to modify our policies and practices in efforts to comply with the GDPR and data protection laws in European Union member states and the United Kingdom, and may incur liabilities, expenses, costs, and other operational losses under in connection with any measures we take to comply with them.

Efforts to ensure that our 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 our 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 our operations are found to be in violation of any of these laws or any other governmental 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 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 our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect 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.

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.

- 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 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 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, in part, applicable 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 made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as information related to ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

- Analogous and related 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, as discussed in the risk factor above, entitled "*Healthcare reform measures could hinder or prevent our product candidates' commercial success.*"

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

Risks Related to Ownership of Our Common Stock

The trading price of our common stock has been highly volatile, and could decline significantly.

The trading price of our common stock has been highly volatile and will likely 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 and the following:

- actual or anticipated results from and any delays in our clinical trials due to the COVID-19 pandemic or other factors, as well as results of regulatory reviews relating to the approval of our product candidates;
- our ability to raise additional capital when needed and the pricing and other terms of such financing, including the substantial amount of ownership dilution that will result from such financing;
- 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;
- 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 public health crises such as pandemics, 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. Such litigation has been, and in the future may be, brought against us, which may result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

The holdings of our stockholders may be substantially diluted, and the prices of our securities may decrease, by future issuances of securities by us.

We will require substantial additional capital beyond our current balance of cash, cash equivalents and short-term investments to fund our Phase 3 trial and our operations beyond the end of 2024. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain substantial additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research and development activities including our planned Phase 3 trial of LUM-201 or to sell or liquidate our assets, and such actions would likely have a material adverse impact on the value of our common stock. To raise required additional capital, we expect to issue additional shares of common stock, preferred stock, restricted stock units (RSUs), or securities convertible into or exchangeable for shares of our common stock. In December 2020, we entered into the Sales Agreement with the Agent, pursuant to which we may offer and sell from time to time through the Agent up to $50.0 million of shares of our common stock from time to time in "at-the-market" offerings. During the year ended December 31, 2023, we sold an aggregate of 181,700 shares under the Sales Agreement, for proceeds of approximately $0.7 million. 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, RSUs, 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 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, 2023, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 49.3% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after December 31, 2023. 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, 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 Bylaws designate the state courts in the State of Delaware or, 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 Bylaws provide 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, 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 do not anticipate that we will pay any cash dividends in the foreseeable future.

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

Provisions in our certificate of incorporation, our Bylaws 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 Bylaws 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 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 Bylaws; and
- the ability of our Board 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.

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.

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 1C. CYBERSECURITY

Risk management and strategy

We have implemented and actively maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including confidential information that is proprietary, and strategic or competitive in nature ("Information Systems and Data").

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: penetration and vulnerability testing, simulations, and other exercises designed to evaluate the effectiveness of our information security processes and improve our security measures.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, our information technology department works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We engage third party auditors to conduct periodic reviews of our security controls protecting our Information Systems and Data, as well as third party penetration testing of our network infrastructure and related systems. The results of these reviews are reported to the audit committee of our Board of Directors.

We use third party service providers to perform information systems and security services, such as developing a vendor management program to manage cybersecurity risks associated with our use of certain vendors. The program includes a review of the security controls and processes used by our vendors. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the service provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a vendor and impose contractual obligations related to data security on the vendor.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part I, "Item 1A. Risk Factors" in this Annual Report on Form 10-K, including "Our business and operations would suffer in the event of system failures, security breaches or cyber-attacks."

Governance

Our Board of Directors addresses our cybersecurity risk management as part of its general oversight function. The nominating and corporate governance committee of our Board of Directors is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain members of our management team, including our director, information technology and our IT security specialist, with input from outside parties specializing in cybersecurity risk. Our director, information technology is responsible for communicating key priorities to relevant personnel and helping to integrate cybersecurity risk considerations into our overall risk management strategy. Our IT security specialist is responsible for reviewing cybersecurity processes and security assessments, preparing security-related reports, and helping prepare for cybersecurity incidents. Our senior IT personnel have expertise in general IT matters and are pursuing certifications in cybersecurity. We utilize third parties for specialized IT matters, including cybersecurity, to augment the expertise of our internal IT personnel.

Our cybersecurity incident response plan is designed to actively monitor and escalate certain cybersecurity incidents to members of management depending on the circumstances, including our chief financial officer and general counsel. Management works with our incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response plan includes reporting to the audit committee of the Board of Directors for certain cybersecurity incidents.

The nominating and corporate governance committee receives periodic reports from our chief financial officer concerning our significant cybersecurity threats and risk and the processes we have implemented to address them. The nominating and corporate governance committee also receives various reports, summaries or presentations related to cybersecurity threats, risks and mitigation.

Item 2. PROPERTIES

We conduct our primary operations at leased facilities described below:

Location	Operations Conducted	Approximate Square Feet	Lease Expiration Date
Austin, Texas	Executive offices	5,000	November 30, 2025
Ames, Iowa	Executive offices	4,200	March 31, 2026

We believe that our administrative office space is adequate to meet our needs for the foreseeable future.

Item 3. LEGAL PROCEEDINGS

In the ordinary course of business, we may be subject from time to time to various proceedings, lawsuits, disputes, or claims. Our practice is to investigate these claims as they arise. Although claims are inherently unpredictable, we are currently not aware of any pending matters that, if determined adversely to us, would individually or taken together, have a material adverse effect on its business, financial position, results of operations, or cash flows.

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 "LUMO".

As of March 1, 2024, we had 66 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.

Issuer Purchases of Equity Securities

On August 17, 2023, we terminated our share repurchase program and we did not repurchase any shares of our common stock during the three months ended December 31, 2023.

Item 6. [RESERVED]

Not applicable.

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 audited consolidated financial statements and notes thereto included in this Annual Report. This Annual Report 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, such statements are subject to the "safe harbor" created by those sections and involve risks and uncertainties. Forward-looking statements are based on our management's beliefs and assumptions and on information available to our management as of the date hereof. As a result of many factors, such as those set forth under Part I, Item 1A "Risk Factors" in this Annual Report, our actual results may differ materially from those anticipated in these forward-looking statements, accordingly, you should not place undue reliance on these forward-looking statements. 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.

Overview

Lumos Pharma, Inc. is a clinical-stage biopharmaceutical company. References in this Annual Report to "us," "we," "our," the "Company," or "Lumos" are to Lumos Pharma, Inc. and its wholly-owned subsidiaries. With our principal executive offices located in Austin, Texas and additional executive and administrative offices located in Ames, Iowa, we are engaged in advancing our clinical program and focused on identifying, acquiring, developing, and commercializing novel products and new therapies for people with rare diseases on a global level, for which there is currently a significant unmet need for safe and effective therapies. Our common stock is listed on the Nasdaq Global Market ("Nasdaq") and trades under the ticker symbol "LUMO."

On March 18, 2020, we closed the business combination (the "Merger") among the Company, formerly known as NewLink Genetics Corporation ("NewLink"), Cyclone Merger Sub, Inc. ("Merger Sub"), a wholly owned subsidiary of NewLink, and Lumos Pharma, Inc., ("Private Lumos") which has since been renamed "Lumos Pharma Sub, Inc." whereby Merger Sub merged with and into Private Lumos, with Private Lumos surviving as a wholly-owned subsidiary of the Company.

Since the consummation of the Merger, we have focused our efforts on the development of our sole product candidate, growth hormone secretagogue ibutamoren ("LUM-201"), a potential oral therapy for idiopathic pediatric growth hormone deficiency ("PGHD") and other rare endocrine disorders.

Our Product Candidate

LUM-201

Our pipeline is focused on the development of an orally administered small molecule, LUM-201, which is a growth hormone ("GH") secretagogue, also called ibutamoren, for rare endocrine disorders where injectable recombinant human growth hormone ("rhGH") is currently approved. LUM-201 is a tablet formulation that will be administered once daily.

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 recombinant growth hormone product injections. 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.

LUM-201 stimulates GH via the GH secretagogue receptor (GHSR1a), also known as the ghrelin receptor, and also suppresses the release of somatostatin, 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 both circulating levels of GH and its down-stream mediator insulin-like growth factor ("IGF-1") which at supraphysiological levels feedbacks or negatively regulates additional release of GH from the pituitary, hence protecting against hyperstimulation of the pituitary.

Overview of PGHD

The PGHD population consists of patients diagnosed with organic PGHD (a more severe GH deficiency) and idiopathic PGHD (a less severe GH deficiency). LUM-201 has been observed to stimulate endogenous GH secretion in patients who have a functional but reduced hypothalamic pituitary GH axis, also known as moderate or idiopathic PGHD patients. We believe that patients with idiopathic PGHD (i.e., those who have a functional but reduced hypothalamic pituitary GH axis) represent approximately 60% of PGHD patients and are expected to respond to LUM-201.

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 (radiation therapy for a 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 and improve body composition, enabling short children to achieve normal height and prevent complications that could involve metabolic abnormalities, cognitive deficits and reduced quality of life. The current standard of care for PGHD is limited to daily subcutaneous injections of rhGH with a treatment cycle lasting up to an average of seven years. Poor compliance with daily rhGH injections during treatment can result in an adverse impact on growth and body composition. In addition to the approval of Skytrofa in 2021, the FDA approved two new once-weekly injection products in 2023, Ngenla and Sogroya, that would reduce the number of injections over the course of treatment for a patient; however, based on our market research, we believe that many providers and patients will have a preference for an orally administered treatment, when available.

Clinical Trial Results and Development Plans

During the fourth quarter of 2020, we launched a program to study the effects of LUM-201 in PGHD and initiated our Phase 2 clinical trial ("OraGrowtH210 Trial" or the "Phase 2 Trial") with the opening of the initial sites participating in this study. The OraGrowtH210 Trial is a global multi-site randomized study evaluating orally administered LUM-201 at three dose levels (0.8, 1.6 and 3.2 mg/kg/day) against a standard dose of daily injectable rhGH in approximately 80 subjects diagnosed with idiopathic PGHD.

The primary endpoint of the study is preliminary validation of our predictive enrichment marker ("PEM") patient selection strategy as evidenced by the percentage of selected patients who grow in response to LUM-201. Each patient enrolled in our Phase 2 clinical trials was given a single dose of LUM-201 at the 0.8 mg/kg/day dose to determine if they meet the cut-off criteria for enrollment, which is a baseline IGF-1 > 30 ng/ml and stimulated GH ≥5 ng/ml. The primary efficacy endpoint is annualized height velocity ("AHV") at six months on treatment with the prediction of growth of 8.3 to 8.6 cm/yr based on historical data for this moderate idiopathic population. Secondary endpoints include selection of a pediatric dose of LUM-201 for future studies including Phase 3 and determination of the degree of repeatability of the PEM selection process in PEM positive patients screened for participation in OraGrowtH210. Consistent with other Phase 2 trials in PGHD, OraGrowtH210 is not powered to show non-inferiority of AHV between Lum-201 and the control arm.

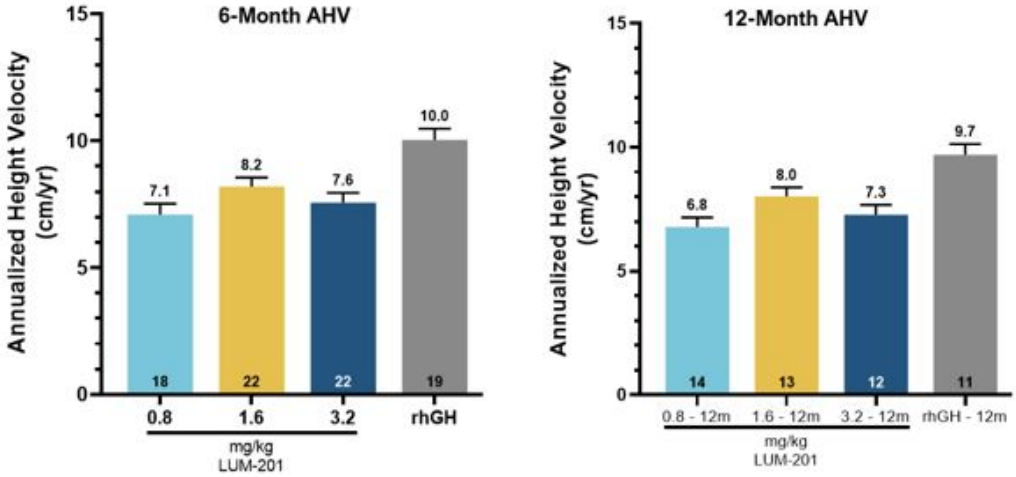
A second concurrent trial of LUM-201 in PGHD exploring the effects of the novel mechanism of action of LUM-201 in amplifying the pulsatile secretion of growth hormone (the "OraGrowtH212 Trial") was initiated in the second quarter of 2021. The OraGrowtH212 Trial in PGHD is being run in parallel with the OraGrowtH210 Trial. The OraGrowtH212 Trial is a single site, open-label trial evaluating the pharmacokinetic and pharmacodynamic ("PK/PD") effects of LUM-201 in up to 24 PGHD subjects at two different dose levels, 1.6 and 3.2 mg/kg/day. The objective of the OraGrowtH212 Trial is to confirm prior clinical data illustrating the increased pulsatile release of endogenous growth hormone unique to LUM-201 and its potential for this mechanism of action to contribute to efficacy in PGHD. Our OraGrowtH212 Trial is being conducted at a single specialized pediatric center with the capacity to conduct the more frequent sample acquisition and monitoring required for this type of clinical trial. Data from the OraGrowtH212 Trial may be supportive in future regulatory filings; however, this trial is not required for regulatory approval of LUM-201. The primary endpoint for this trial is six months of PK/PD and height velocity data in up to 24 subjects. As we announced on February 28, 2023, we completed enrollment for this trial with 22 subjects.

During the first quarter of 2022, we initiated our OraGrowtH213 Trial (the "OraGrowtH213 Trial," and together with the OraGrowtH210 Trial, the OraGrowtH211 Trial, and the OraGrowtH212 Trial, the "OraGrowtH Trials"), an open-label, multi-center, Phase 2 study evaluating the growth effects and safety of LUM-201 following 12 months of daily rhGH in up to 20 idiopathic PGHD subjects who have completed the OraGrowtH210 Trial. Subjects will be administered LUM-201 at a dose level of 3.2 mg/kg/day for up to 12 months.

On November 7, 2023, we announced that topline results from our Phase 2 OraGrowtH210 dose-finding trial and our Phase 2 OraGrowtH212 PK/PD trial each met all primary and secondary endpoints. We believe this data supports advancing our plans to initiate a Phase 3 trial which is anticipated to begin in the second half of 2024, dependent upon a successful FDA End of Phase 2 meeting which is anticipated in the second quarter of 2024, and successful completion of a financing transaction resulting in sufficient proceeds to us.

OraGrowtH210 Topline Results Highlights

Our OraGrowtH210 trial met its primary objective, with 6-month AHV data of 8.2 cm/yr supporting the 1.6 mg/kg as the optimal dose for a Phase 3 clinical trial.[1] The 6-month and 12-month AHV on 1.6 mg/kg/day met expectations for growth and were within the targeted 2.0 cm/yr margin for non-inferiority against injectable rhGH cohort.



ANCOVA Model Terms: treatment, Age at dose 1, Sex, Baseline HT SDS, Baseline BMI SDS, Baseline IGF-1 SDS, LUM-201 PEM, Baseline BA Delay, HT SDS-MPH SDS Bars represent Least Squares Mean (LSM), Error bars represent the Standard Error of LSM

- Dosage at 1.6 mg/kg demonstrates highest LUM-201 AHV at six months and 12 months
- 1.7 cm/yr difference between 1.6 mg/kg LUM-201 dose and rhGH comparator arm at 12 months falls within historical non-inferiority Phase 3 margins
- LUM-201 AHVs align with historical growth rates of rhGH in patient populations with similar characteristics
- 12-month AHV data available for 50/81 subjects: Growth rates durable at 12 months

The mean AHVs at 6 months and 12 months observed in the 1.6 mg/kg dose LUM-201 arm were 8.2 cm/yr and 8.0 cm/yr, respectively. These AHVs were in line with our expectations for 8.3-8.6 cm/yr AHV observed after 12 months of rhGH treatment in a moderate PGHD patient population.[2-4]

The higher than anticipated AHV seen in this moderate PGHD population treated in the rhGH control arm of the OraGrowtH210 Trial was inconsistent with multiple historical trials which predicted growth in the 8.3-8.6 cm/yr range for moderate PGHD[2-5]. This distinctive growth pattern observed in the daily GH arm of this study is likely due to a higher dosage and the presence of outliers. We anticipate that in a larger, more statistically robust Phase 3 trial, the AHV associated with rhGH treatment will align more closely with historical values for the moderate patient population.

[1] For all OraGrowtH Trial AHV values, ANCOVA Model Terms: treatment, Age at dose 1, Sex, Baseline HT SDS, Baseline BMI SDS, Baseline IGF-1 SDS, LUM-201 PEM, Baseline BA Delay, for graphs HT SDS-MPH SDS Bars represent Least Squares Mean (LSM), Error bars represent the Standard Error of LSM
[2] Blum et al JES 2021
[3] Lechuga-Sancho et al JPEM 2009
[4] Ranke et al JCEM 2010
[5] Bright et al JES 2021

The OraGrowtH210 Trial met the prespecified percent responder enrichment providing preliminary validation of the PEM strategy. Additionally, we have achieved a 100% success rate in meeting the predetermined outcome for positive PEM specification classification reproducibility.

OraGrowtH212 Topline Results Highlights

The topline results from our OraGrowtH212 Trial reveal that LUM-201 achieved an expected AHV with only 20% of the growth hormone (GH) concentration observed using injectable rhGH. This outcome was achieved through LUM-201's natural

pulsatile mechanism, promoting growth in moderate PGHD subjects that align with historical norms. Notably, LUM-201 raised circulating GH to levels closer to normal physiological ranges,[6] whereas treatment with injectable rhGH has been shown to elevate GH levels to four to five times that of typical healthy children.[7] Furthermore, we believe it is important to highlight that during the first 12 months of LUM-201 treatment, no IGF-1 values exceeded 2 standard deviations from the mean.

Combined 24-Month Data from OraGrowtH210 and OraGrowtH212 Trials

- Eighteen and 24-month growth data were available for 10 subjects from the OraGrowtH210 and OraGrowtH212 Trials who met AHV criteria per protocol at 12 months.
- Combined data from the 1.6 mg/kg and 3.2 mg/kg cohorts of both trials demonstrate sustained AHVs from 12 to 24 months without a considerable decline in growth velocity compared to the previously reported ~20% decline in AHV on rhGH from 12 to 24 months observed in the Pfizer Phase 4 KIGS dataset.[4]

Safety & Tolerability Highlights

The topline results from both the OraGrowtH210 and OraGrowtH212 trials have shown a clean safety record, characterized by an absence of treatment-related Serious Adverse Events ("SAE's"), no instances of participants discontinuing treatment due to adverse events (AEs), and the absence of any significant safety concerns in various parameters such as laboratory values, adverse event data, or in electrocardiogram ("ECG") readings.

[4] Ranke et al JCEM 2010
[6] Zadik et al Horm Res 1992
[7] Adapted from data in Albertsson-Wikland et al JCEM 1994; 24h exposures listed reflect absorbance/bioavailability of ~60% of the administered dose

Intellectual Property

Lumos acquired LUM-201 from Ammonett Pharma LLC ("Ammonett") in July 2018. LUM-201 received an Orphan Drug Designation ("ODD") in the United States and the European Union for Growth Hormone Deficiency ("GHD") in 2017. The United States patent "Detecting and Treating Growth Hormone Deficiency" has been issued with an expiration in 2036. Related patents have been issued in the European Union, Australia, Israel, Japan, South Korea, Hong Kong, Singapore, and Ukraine, with related patent applications pending in multiple other jurisdictions. In November 2022, we filed a patent application titled "Compactable Oral Formulations of Ibutamoren," which contains claims directed to certain improved LUM-201 drug product formulations we intend to utilize in our LUM-201 Phase 3 trial and ultimately commercialize. The novel formulation takes advantage of unique properties of LUM-201, namely the ability to compress a desired quantity of drug product into a tablet smaller than typical tablets. We believe the compressed tablet will enable a commercial product offering well suited for the full range of potential patient preferences and will result in a reduced treatment burden for the patient population. The patent application is currently pending and if granted, would provide composition of matter protection through November 2042 for the commercialized version of LUM-201.

In February 2024, we filed a provisional patent application titled "Pharmaceutical Formulations for Maintaining Lean Muscle Mass During Weight Loss Treatment," which contains claims directed to the use of LUM-201 in combination with a glucagon-like peptide 1 ("GLP-1") receptor agonist or a dual GLP-1/glucose-dependent insulinotropic polypeptide ("GIP") agonist. The novel combination takes advantage of unique properties of LUM-201, including inhibition of myostatin signaling, the ability to reverse diet-induced nitrogen wasting in humans, and the ability to generate sustained increases in serum levels of growth hormone, IGF-1 and IGF-binding protein-3. We believe combination has the potential to improve GLP-1 treatment by minimizing reductions in lean mass while improving body composition by increasing the proportion of lean to fat mass. The provisional patent application has been filed and any patents granted, would provide protection through February 2044 for the combined therapies utilizing LUM-201 and GLP-1.

Financial Overview

Revenue

We have no products approved for commercial sale and have not generated any revenue from product sales. In the future, we may generate revenue from product sales, or license fees, milestones, or other upfront payments if we enter into any collaborations or license agreements. We may also continue to generate revenue from royalties on product sales. We expect that our future revenue will fluctuate from quarter to quarter for many reasons, including the uncertain timing and amount of any such payments and sales.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred to advance our product candidate, LUM-201. Our research and development expenses include internal personnel expenditures along with external research and development expenses incurred under arrangements with third parties, such as contract research and manufacturing organizations, consultants, and our scientific advisors.

We expense research and development costs as incurred. Nonrefundable advance payments for goods and services that will be used in future research and development activities are capitalized as an asset and expensed when the service has been performed or when the goods have been received. We expect our research and development expenses to increase for the foreseeable future as we continue to prepare for and conduct our LUM-201 Phase 3 clinical trial and develop our pipeline and pursue regulatory approval of other indications for LUM-201.

General and Administrative Expenses

General and administrative expenses consist primarily of professional fees for legal, auditing, tax and business consulting services, personnel expenses and travel costs. We expect that general and administrative expenses will increase in the future as we expand our operating activities to prepare for and conduct our LUM-201 Phase 3 clinical trial.

Results of Operations

Comparison of the Year Ended December 31, 2023 and 2022

	Year Ended December 31,			
	2023	2022	Change in $	Change in %
	(in thousands)		(in thousands)	
Revenues:				
Royalty revenue	$2,051	$1,523	528	35 %
Total revenues	2,051	1,523		
Operating expenses:				
Research and development	22,096	17,857	4,239	24 %
General and administrative	16,569	15,706	863	5 %
Total operating expenses	38,665	33,563		
Other income, net	2,551	965	1,586	164 %
Income tax benefit	29	13	16	123 %
Net loss	$ (34,034)	$ (31,062)		

Revenues. Royalty revenues increased $0.5 million for the year ended December 31, 2023 compared to the same period in 2022 due to royalties earned related to sales of ERVEBO®.

Research and Development Expenses. Research and development expenses increased by $4.2 million for the year ended December 31, 2023 compared to the same period in 2022 primarily due to increases of $3.3 million in clinical trial expenses, $0.9 million in contract manufacturing expenses, $0.2 million in consulting expenses and $0.2 million in other expenses, partially offset by a $0.4 million decrease in personnel-related expenses.

General and Administrative Expenses. General and administrative expenses increased by $0.9 million for the year ended December 31, 2023 compared to the same period in 2022 primarily due to increases of $0.5 million in personnel-related expenses, $0.4 million in royalty expenses and $0.1 million in travel expenses, partially offset by a $0.1 million decrease in other expenses.

Other Income, net. Other income, net increased by $1.6 million for the year ended December 31, 2023 compared to the same period in 2022 primarily due to an increase in interest income in 2023 driven by an increase in interest rates and short-term investments.

Liquidity and Capital Resources

We have historically devoted substantially all of our efforts toward research and development and have never earned revenue from commercial sales of our products. We expect to continue to incur additional substantial losses in the foreseeable

future as a result of our research and development activities, including preparing for and conducting our LUM-201 Phase 3 trial. As of December 31, 2023, we had approximately $36.1 million of cash, cash equivalents and short-term investments. Our accumulated deficit as of December 31, 2023 was approximately $161.5 million. Given our current development plans and cash management efforts, we anticipate our cash resources will be sufficient to fund operations through the third quarter of 2024. However, based on our current cash forecast and our dependence on our ability to obtain additional financing to fund our operations in advancing our PGHD program into a Phase 3 trial, we concluded that our available cash, cash equivalents and short-term investments as of December 31, 2023 may not be sufficient to fund our operations for at least 12 months from the filing date of this Annual Report, and thus substantial doubt exists as to our ability to continue as a going concern.

If available liquidity becomes insufficient to meet our obligations as they come due, our management's plan is to raise additional equity or financing to fund our future operations. There can be no assurances that such financing will be available on terms that are favorable to us, or at all. If we are unable to raise additional funding to meet our working capital needs in the future, we will be forced to delay or reduce the scope of our research programs, including our LUM-201 Phase 3 trial, and/or limit or cease our operations.

We will require substantial additional capital beyond our current balance of cash, cash equivalents and short-term investments to fund our Phase 3 trial and our operations beyond the end of the third quarter of 2024. Assuming our current Phase 3 clinical trial plan is approved by the FDA, we estimate the capital needed to fund our current operations and the PGHD program through the fourth quarter of 2026 will be approximately $85.0 million to $100.0 million. We plan to finance our operations and our Phase 3 trial through the sale of additional equity or debt securities, a credit facility or one or more strategic alliances. The sale of additional equity or convertible debt securities would result in substantial ownership 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. Any such required additional capital may not be available on reasonable terms, if at all. If we are 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 or to sell or liquidate our assets, and such actions would likely have a material adverse impact on the value of our common stock.

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:

- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- 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;
- 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;
- changes in domestic and global business or macro-economic conditions, including any further adverse impacts from the COVID-19 pandemic or military conflict, resulting labor shortages, supply chain disruptions, and inflation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

On December 30, 2020, we entered into a Controlled Equity Offering^{SM} Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co., as agent (the “Agent”), pursuant to which we may offer and sell from time to time through the Agent up to $50.0 million of shares of our common stock (the “Shares”). The offering and sale of the Shares has been registered under the Securities Act. Under the Sales Agreement, the Agent may sell the Shares by any method permitted by law and deemed to be an “at-the-market” offering as defined in Rule 415(a)(4) promulgated under the Securities Act, including sales made directly on or through the Nasdaq, on any other existing trading market for the Shares, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices and/or any other method permitted by law. We

will notify the Agent of the number of Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Shares that may be sold in any one day and any minimum price below which sales may not be made. We intend to use the net proceeds from this offering for working capital and general corporate purposes, which include, but are not limited to, funding our Phase 3 clinical trial for LUM-201 and evaluating and pursuing development opportunities for our product candidate into potential additional indications. We may also use a portion of the net proceeds to invest in future strategic transactions to expand and diversify our product pipeline through the acquisition or licensing of product candidates or technologies that are complementary to our own. We will pay the Agent a commission of up to 3.0% of the gross sales price of the Shares sold through it under the Sales Agreement. In addition, we have agreed to reimburse certain expenses incurred by the Agent in connection with the offering. The Sales Agreement may be terminated by the Agent or by us at any time upon notice to the other party, as set forth in the Sales Agreement, or by the Agent at any time in certain circumstances, including the occurrence of a material and adverse change in our business or financial condition that makes it impractical or inadvisable to market the shares or to enforce contracts for the sale of the Shares. Under our Prospectus Supplement dated August 26, 2022, we may sell up to $17.8 million of Shares under the Sales Agreement. As of December 31, 2022, no shares had been issued under the Sales Agreement. During the year ended December 31, 2023, we sold an aggregate of 181,700 shares under the Sales Agreement, for proceeds of approximately $0.7 million.

So long as our public float is less than $75.0 million, we will be subject to the restrictions set forth in General Instruction I.B.6 to Form S-3, which limit our ability to conduct primary offerings under a Form S-3 registration statement, including with respect to issuances under our at-the-market program under the Sales Agreement. Under such limitations, we may not sell, during any 12-month period, securities on Form S-3 having an aggregate market value of more than one-third of our public float. As of March 1, 2024, our public float calculated in accordance with General Instruction I.B.6 of Form S-3 was $19.7 million.

On August 16, 2022, we announced that our board of directors had authorized a share repurchase program, under which we may purchase up to $3.0 million shares of our outstanding common stock. During the years ended December 31, 2023 and 2022, we repurchased an aggregate of 379,942 shares for approximately $1.3 million, and an aggregate of 137,526 shares for approximately $0.7 million, respectively. All such purchases were made through open-market transactions with shares effectively retired upon repurchase. On August 17, 2023, we terminated our share repurchase program.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below (in thousands):

	Year Ended December 31,	
	2023	**2022**
Net cash used in operating activities	$ (31,095)	$ (26,623)
Net cash provided by (used in) investing activities	10,742	(11,358)
Net cash used in financing activities	(576)	(821)
Net decrease in cash and equivalents	$ (20,929)	$ (38,802)

For the years ended December 31, 2023 and 2022, our operating activities used cash of $31.1 million and $26.6 million, respectively. The increase was primarily due to a $3.0 million increase in losses from operations, a $1.1 million decrease in net cash inflow from the change in working capital, and a $0.4 million decrease in adjustments to reconcile net loss to net cash used in operating activities, primarily due to an increase of $0.4 million in other income, net.

For the years ended December 31, 2023 and 2022, our investing activities provided cash of $10.7 million and used cash of $11.4 million, respectively. The increase was primarily due to $18.1 million in cash provided by short-term investment maturities offset by $7.4 million in cash used for short-term investment purchases during the year ended December 31, 2023, compared to $11.3 million in cash used for purchases of short-term investments during the same period in 2022.

For the years ended December 31, 2023 and 2022, our financing activities used net cash of $0.6 million and $0.8 million, respectively. The decrease was primarily due to an $0.8 million increase in net cash proceeds from the sale of common stock under the Controlled Equity Offering^{SM} during the year ended December 31, 2023, partially offset by a $0.6 million increase in cash paid for common stock repurchases during the year ended December 31, 2023.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations are based on our consolidated financial statements which have prepared our consolidated financial statements in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported

amount of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments. We based our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results could, therefore, differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to the consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of the consolidated financial statements.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist primarily of employee-related expenses, which include salaries, bonuses, benefits and stock-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. Advance payments for goods or services to be rendered in the future for use in research and development 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.

Expenses Accrued Under Contractual Arrangements with Third Parties; Accrued Clinical Expenses

We estimate our 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.

We base our 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 our behalf. Invoicing from third-party contractors for services performed can lag several months. We accrue the costs of services rendered in connection with third-party contractor activities based on our 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 in the period in which they become known through operations.

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, 2023 and December 31, 2022, we had cash, cash equivalents and short-term investments of $36.1 million and $67.4 million, respectively, consisting primarily of money market funds, commercial paper, corporate debt securities and U.S. government and agency securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. Throughout 2022, the Federal Reserve increased rates to a target range of 4.25% to 4.50% in response to rising inflation. During 2023, the Federal Reserve continued to increase rates to a target range of 5.25% to 5.50%. 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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

LUMOS PHARMA, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm (KPMG LLP, Austin, TX, PCAOB ID#: 185)	78
Consolidated Balance Sheets as of December 31, 2023 and 2022	79
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2023 and 2022	80
Consolidated Statements of Changes in Stockholders' Equity for the Years Ended December 31, 2023 and 2022	81
Consolidated Statements of Cash Flows for the Years Ended December 31, 2023 and 2022	82
Notes to Consolidated Financial Statements	83

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Lumos Pharma, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Lumos Pharma, Inc. and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements 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 audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ KPMG LLP

We have served as the Company's auditor since 2015.

Austin, Texas
March 7, 2024

Lumos Pharma, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 35,078	$ 56,007
Short-term investments	999	11,352
Prepaid expenses and other current assets	3,748	4,427
Other receivables	210	223
Total current assets	40,035	72,009
Non-current assets:		
Property and equipment, net	—	53
Right-of-use asset	603	230
Total assets	$ 40,638	$ 72,292
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 890	$ 275
Accrued expenses	5,858	6,200
Current portion of lease liability	282	233
Total current liabilities	7,030	6,708
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	303	—
Total liabilities	13,333	12,708
Commitments and contingencies		
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at December 31, 2023 and 2022; issued and outstanding shares - 0 at December 31, 2023 and 2022	—	—
Common stock, $0.01 par value: Authorized shares - 75,000,000 at December 31, 2023 and 2022; issued shares - 8,125,728 and 8,283,708 at December 31, 2023 and 2022, respectively, and outstanding shares - 8,102,555 and 8,267,968 at December 31, 2023 and 2022, respectively	81	82
Treasury stock, at cost, 23,173 and 15,740 shares held as of December 31, 2023 and 2022, respectively	(196)	(170)
Additional paid-in capital	188,937	187,164
Accumulated deficit	(161,517)	(127,483)
Accumulated other comprehensive loss	—	(9)
Total stockholders' equity	27,305	59,584
Total liabilities and stockholders' equity	$ 40,638	$ 72,292

See accompanying notes to consolidated financial statements.

Lumos Pharma, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year Ended December 31,	
	2023	**2022**
Revenues:		
Royalty revenue	$ 2,051	$ 1,523
Total revenues	2,051	1,523
Operating expenses:		
Research and development	22,096	17,857
General and administrative	16,569	15,706
Total operating expenses	38,665	33,563
Loss from operations	(36,614)	(32,040)
Other income and expense:		
Other income, net	683	91
Interest income	1,868	874
Other income, net	2,551	965
Net loss before taxes	(34,063)	(31,075)
Income tax benefit	29	13
Net loss	$ (34,034)	$ (31,062)
Net loss per share:		
Basic and diluted	$ (4.18)	$ (3.71)
Weighted average number of common shares outstanding		
Basic and diluted	8,145,155	8,373,821
Other comprehensive income (loss):		
Unrealized gain (loss) on short-term investments	9	(9)
Total comprehensive loss	$ (34,025)	$ (31,071)

See accompanying notes to consolidated financial statements.

Lumos Pharma, Inc.
Consolidated Statement of Changes in Stockholders' Equity
(In thousands, except share data)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	8,357,391	$ 83	9,428	$ (114)	$ 185,429	$ (96,421)	$ —	$ 88,977
Stock-based compensation	—	—	—	—	2,320	—	—	2,320
Exercise of stock options	17,288	—	—	—	40	—	—	40
Stock issued upon vesting of restricted stock units	25,771	—	—	—	—	—	—	—
Shares surrendered for tax withholding on vested awards	(6,312)	—	6,312	(56)	—	—	—	(56)
Stock issued under stock purchase plan	11,356	—	—	—	49	—	—	49
Repurchases of common stock	(137,526)	(1)	—	—	(674)	—	—	(675)
Other comprehensive loss	—	—	—	—	—	—	(9)	(9)
Net loss	—	—	—	—	—	(31,062)	—	(31,062)
Balance at December 31, 2022	8,267,968	$ 82	15,740	$ (170)	$ 187,164	$ (127,483)	$ (9)	$ 59,584
Stock-based compensation	—	—	—	—	2,322	—	—	2,322
Stock issued under the Controlled Equity Offering℠, net of costs	181,700	2	—	—	723	—	—	725
Stock issued upon vesting of restricted stock units	27,564	—	—	—	—	—	—	—
Shares surrendered for tax withholding on vested awards	(7,433)	—	7,433	(26)	—	—	—	(26)
Stock issued under stock purchase plan	12,698	—	—	—	35	—	—	35
Repurchases of common stock	(379,942)	(3)	—	—	(1,307)	—	—	(1,310)
Other comprehensive income	—	—	—	—	—	—	9	9
Net loss	—	—	—	—	—	(34,034)	—	(34,034)
Balance at December 31, 2023	8,102,555	$ 81	23,173	$ (196)	$ 188,937	$ (161,517)	$ —	$ 27,305

See accompanying notes to consolidated financial statements.

Lumos Pharma, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2023	**2022**
Cash Flows From Operating Activities		
Net loss	$ (34,034)	$ (31,062)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,322	2,320
Depreciation and amortization	44	49
Other income, net	(392)	(26)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	679	492
Other receivables	13	(92)
Accounts payable and accrued expenses	273	1,696
Net cash used in operating activities	(31,095)	(26,623)
Cash Flows From Investing Activities		
Purchases of marketable securities	(7,378)	(11,337)
Maturities of marketable securities	18,120	—
Purchase of equipment	—	(21)
Net cash provided by (used in) investing activities	10,742	(11,358)
Cash Flows From Financing Activities		
Exercise of stock options	—	40
Sale of shares under stock purchase plans	35	49
Payment for tax withholding on vested awards	(26)	(56)
Repurchases of common stock	(1,310)	(675)
Sale of shares under Controlled Equity Offering℠, net of costs	725	—
Payment of offering costs under Controlled Equity Offering℠	—	(179)
Net cash used in financing activities	(576)	(821)
Net decrease in cash and cash equivalents	(20,929)	(38,802)
Cash and cash equivalents at beginning of year	56,007	94,809
Cash and cash equivalents at end of year	$ 35,078	$ 56,007

See accompanying notes to consolidated financial statements.

1. Description of Business

Organization and Nature of operations

Lumos Pharma, Inc. is a clinical-stage biopharmaceutical company. References in this Annual Report to "us," "we," "our," the "Company," or "Lumos" are to Lumos Pharma, Inc. and its wholly-owned subsidiaries. With our principal executive offices located in Austin, Texas and additional executive and administrative offices located in Ames, Iowa, we are engaged in advancing our clinical program and focused on identifying, acquiring, developing, and commercializing novel products and new therapies for people with rare diseases on a global level, for which there is currently a significant unmet need for safe and effective therapies. Our common stock is listed on the Nasdaq Global Market ("Nasdaq") and trades under the ticker symbol "LUMO."

The Company entered into a business combination (the "Merger") between the Company, formerly known as NewLink Genetics Corporation ("NewLink"), Cyclone Merger Sub, Inc. ("Merger Sub"), a wholly owned subsidiary of NewLink, and Lumos Pharma, Inc., which has since been renamed "Lumos Pharma Sub, Inc." ("Private Lumos"). The Merger closed on March 18, 2020, and Merger Sub merged with and into Private Lumos, with Private Lumos surviving as a wholly-owned subsidiary of the Company. Immediately prior to the closing of the Merger, the shares of NewLink common stock were adjusted with a reverse split ratio of 1-for-9. Under the terms of the Merger, Private Lumos stockholders received an aggregate of 4,146,398 shares of NewLink common stock (after giving effect to the reverse split) for each share of outstanding common stock, Series A Preferred Stock and Series B Preferred Stock of Private Lumos converted at an exchange ratio of 0.1308319305, 0.0873621142 and 0.1996348626, respectively. Immediately following the reverse stock split and the completion of the Merger, there were 8,292,803 shares of the Company's common stock outstanding, of which approximately 50% was held by each of Private Lumos and NewLink security holders. The Merger was accounted for as a reverse asset acquisition.

After the consummation of the Merger, the combined company has focused its efforts on the development of Private Lumos' sole product candidate, secretagogue ibutamoren ("LUM-201"), a potential oral therapy for idiopathic pediatric growth hormone deficiency ("PGHD") and other rare endocrine disorders.

Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements also do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. The Company has historically devoted substantially all of its efforts toward research and development and has never earned revenue from commercial sales of its products. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities.

As of December 31, 2023, the Company had approximately $36.1 million of cash, cash equivalents and short-term investments. The Company's accumulated deficit at December 31, 2023 was approximately $161.5 million. Given its current development plans and cash management efforts, the Company anticipates its cash resources will be sufficient to fund operations through the third quarter of 2024.

However, based on the Company's current cash forecast and the Company's dependence on its ability to obtain additional financing to fund its operations in advancing the PGHD program into a Phase 3 trial, the Company concluded that its available cash, cash equivalents and short-term investments as of December 31, 2023 may not be sufficient to fund its operations for at least 12 months from the filing date of this Annual Report, and thus substantial doubt exists as to the Company's ability to continue as a going concern.

If the Company is not able to raise additional funding and its available liquidity becomes insufficient to meet the Company's obligations as they come due, management's plan is to raise additional equity or financing to fund the Company's future operations. There can be no assurances that such financing will be available on terms that are favorable to the Company, or at all. If the Company is unable to raise additional funding to meet its working capital needs in the future, it will be forced to delay or reduce the scope of its research programs, including its LUM-201 Phase 3 trial, and/or limit or cease its operations.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements include the accounts of Lumos and its wholly-owned subsidiaries and have been prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP"). All significant intercompany accounts and transactions are eliminated in consolidation. In the opinion of management, all adjustments of a normal and recurring nature considered necessary for a fair presentation have been included in the accompanying consolidated financial statements.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. Significant management estimates that affect the reported amounts of assets and liabilities include stock-based compensation, accruals for clinical trials and deferred tax assets. While we believe that the estimates and assumptions used in preparation of our consolidated financial statements based on our knowledge of current events and actions that we may undertake in the future are appropriate, actual results could differ from those estimates, and any such differences may be material.

Fair Value of Financial Instruments and Credit Risk

The fair values of the Company's financial instruments are recorded using a hierarchical disclosure framework based upon the level of subjectivity of the inputs used in measuring assets and liabilities. The three levels are described below:

- Level 1: Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2: Inputs other than Level 1 that are directly or indirectly observable, such as quoted prices for similar assets or liabilities and quoted prices in less active markets.
- Level 3: Inputs are unobservable for the asset or liability and are developed based on the best information available in the circumstances, which might include the Company's own data.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash deposits, certificates of deposit, money market funds and investments in debt securities with original maturities of ninety days or less when purchased.

Investments

Management determines the appropriate classification of its available-for-sale investments in debt securities at the time of purchase. Generally, investments with original maturities greater than ninety days at the date of purchase are classified as short-term because it is management's intent to use the investments to fund current operations or to make them available for current operations. Investments in available-for-sale securities are reported at fair value, with unrealized gains and losses, net of tax, recorded as a component of accumulated other comprehensive loss in the Consolidated Balance Sheet.

The Company reviews its available-for-sale investments as of the end of each reporting period for declines in fair value based on the specific identification method. The Company records an allowance for credit loss when a decline in fair value is due to credit-related factors. The Company considers various factors in determining whether an investment is impaired, including the severity of the impairment, changes in underlying credit ratings, forecasted recovery, its intent to sell or the likelihood that it would be required to sell the investment before its anticipated recovery in market value and the probability that the scheduled cash payments will continue to be made. When the Company concludes that a credit-related impairment has occurred, the Company assesses whether it intends to sell the security or if it is more likely than not that it will be required to sell the security before recovery. If either of these two conditions is met, the Company recognizes a charge in net loss equal to the entire difference between the security's amortized cost basis and its fair value. If the Company does not intend to sell a

security and it is not more likely than not that it will be required to sell the security before recovery, the unrealized loss is separated into an amount representing the credit loss, which is recognized in net loss, and the amount related to all other factors, which is recorded in accumulated other comprehensive income loss.

Leases

The Company determines if an arrangement is a lease at inception. Operating lease right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expenses for lease payments are recognized on a straight-line basis over the lease term. (See Note 6.)

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.

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.

Stock-Based Compensation

Stock options and performance stock options

The Company recognizes compensation costs related to stock options granted to employees and non-employees based on the estimated fair value of the awards on the date of grant. The Company estimates the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The Company records forfeitures as they are incurred. The grant date fair value of the stock options is expensed on a straight-line basis over the applicable vesting period, which generally is four years. The fair value of performance-based stock options is 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 assumptions used in Black-Scholes option-pricing model are as follows:

- *Fair Market Value of Common Stock*. The grant date fair market value is the quoted market price of the Company's common stock.
- *Expected term*. The expected term of stock options represents the period that the stock options are expected to remain outstanding and is based on vesting terms, exercise term and contractual lives of the options. The expected term is based on the simplified method and is estimated as the average of the weighted average vesting term and the time to expiration as of the grant date.
- *Expected volatility*. Given the low trading volume in the Company's common stock, the Company uses a blended volatility based both on its own historical data and the trading history from the common stock of a set of comparable publicly-listed biopharmaceutical companies. Volatility for employee stock purchase plan ("ESPP") shares is equal to the Company's historical volatility over the six-month offering period.
- *Risk-free interest rate*. The risk-free interest rate is based on the U.S. Treasury yield with a maturity equal to the expected term of the stock options in effect at the time of grant.
- *Dividend yield*. The expected dividend is assumed to be zero as the Company has never paid dividends and has no current plan to pay any dividends on its common stock.

Restricted stock units

Service-based restricted stock units are valued using the market price of our common stock on the grant date. The grant date fair value of the restricted stock units is expensed on a straight-line basis over the applicable vesting period, which generally is four years.

Employee stock purchase plan

Our ESPP allows employees to purchase common stock at a 15% discount from the lower of the common stock closing price on the first or last day of the offering period. The current offering period is from July 1, 2023 to June 30, 2025. We use the Black-Scholes Model to determine fair value, which incorporates assumptions as described above. The grant date fair value of the ESPP is expensed on a straight-line basis over the applicable vesting period, which generally is six months.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share reflects the potential dilution, using the treasury stock method.

Revenue Recognition

For arrangements that may include sales-based royalties, including milestone payments based on the level of sales, we recognize revenue at the later of (i) when the related sale has occurred or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist primarily of employee-related expenses, which include salaries, bonuses, benefits and stock-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. Advance payments for goods or services to be rendered in the future for use in research and development 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.

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.

3. License and Asset Purchase Agreements

License and LUM-201 Asset Purchase Agreements

In July 2018, the Company entered into an asset purchase agreement (the "APA") with Ammonett and acquired substantially all of the assets related to LUM-201, which Ammonett licensed from Merck in October 2013 (the "Lumos Merck Agreement").

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.

On August 12, 2020, we entered into Amendment No. 1 to the Lumos Merck Agreement with Merck (the "Lumos Merck Agreement Amendment"). Pursuant to the Lumos Merck Agreement Amendment, we obtained from Merck a worldwide, non-exclusive, sublicensable (subject to Merck's consent in the United States, specified major European countries and Japan, such consent not to be unreasonably withheld) license under the specified patents and know-how that are the subject of our exclusive license to develop, manufacture and commercialize LUM-201 for diagnostic purposes, excluding Autism Spectrum Disorders.

Under the APA, the Company paid Ammonett an upfront fee of $3.5 million which was recorded as research and development expense in 2018. The Company may also incur development milestone payments totaling up to $17.0 million for achievement of specified milestones on the first indication that Lumos pursues and up to $14.0 million for achievements of specified milestones on the second indication that Lumos pursues, sales milestone payments totaling up to $55.0 million on worldwide product sales, and royalty payments based on worldwide product sales, as discussed below.

Under the Lumos Merck Agreement, 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 indication that Lumos pursues and up to $8.5 million for the second indication that Lumos pursues. Tiered sales milestone payments totaling up to $80.0 million are required on worldwide net product sales up to $1.0 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 Merck License 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.

License and PRV Asset Purchase Agreements

In November 2014, NewLink entered into a worldwide license and collaboration agreement (the "NewLink Merck Agreement"), with Merck, to develop and potentially commercialize its Ebola vaccine rVSVΔG-ZEBOV that it licensed from the Public Health Agency of Canada ("PHAC"). rVSVΔG-ZEBOV was also eligible to receive a PRV if approval was granted by the U.S. Food and Drug Administration (the "FDA"), with the Company entitled to 60% and Merck entitled to the remaining 40% of the PRV value obtained through sale, transfer or other disposition of the PRV. On December 20, 2019, Merck announced that 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 and grant of the PRV.

Under the NewLink Merck Agreement, as amended, the Company has earned and has the potential to continue to earn royalties on sales of the vaccine in certain countries. However, we believe that the market for the vaccine will be limited primarily to areas in the developing world that are excluded from royalty payment or where the vaccine is donated or sold at low or no margin and, therefore, we do not expect to receive material royalty payments from Merck in the foreseeable future. For the years ended December 31, 2023 and 2022, the Company recognized revenues of $2.0 million and $1.5 million, respectively, for royalties related to royalty-bearing commercial sales of the vaccine.

Additionally, per the terms of the licensing agreement with the PHAC, the Company has an obligation to pay a royalty fee to the PHAC for any royalty amounts earned. For the years ended December 31, 2023 and 2022, the Company paid the PHAC $1.3 million and $1.0 million, respectively, for royalties related to royalty-bearing commercial sales of the vaccine. Royalty expenses are included within general and administrative expenses in the consolidated statement of operations.

4. Financial Instruments

Fair Value

The following summarizes the valuation of the Company's financial instruments (in thousands). The tables do not include either cash on hand or assets and liabilities that are measured at historical cost or any basis other than fair value.

	As of December 31, 2023		
	Level 1	**Level 2**	**Total**
Cash equivalents:			
Money market funds	$ 34,741	$ —	$ 34,741
Total cash equivalents	$ 34,741	$ —	$ 34,741
Short-term investments:			
U.S. government and agency securities	$ —	$ 999	999
Total short-term investments	$ —	$ 999	$ 999
Total	$ 34,741	$ 999	$ 35,740

	As of December 31, 2022		
	Level 1	**Level 2**	**Total**
Cash equivalents:			
Money market funds	$ 52,045	$ —	$ 52,045
Corporate debt securities	—	2,497	2,497
Non-U.S. debt securities	—	800	800
Total cash equivalents	$ 52,045	$ 3,297	$ 55,342
Short-term investments:			
Commercial paper	$ —	$ 2,909	$ 2,909
U.S. government and agency securities	2,451	5,992	8,443
Total short-term investments	$ 2,451	$ 8,901	$ 11,352
Total	$ 54,496	$ 12,198	$ 66,694

As of December 31, 2023 and 2022, the Company had no Level 3 assets or liabilities. There were no transfers between Level 1, Level 2, or Level 3 measurements for the years ending December 31, 2023 and 2022.

The Company's other financial instruments, including cash, receivables and accounts payable, are recorded at amounts that approximate their fair values due to their short maturities. The Company is unable to estimate the fair value of the royalty obligation to Iowa Economic Development Authority based on future product sales, as the timing of payments, if any, is uncertain.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents and short-term investments. Cash and cash equivalents and investments in marketable securities are invested in accordance with the Company's cash investment policy with the primary objective being the preservation of capital and maintenance of liquidity. The cash investment policy includes guidelines on the quality of financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company limits its exposure to credit loss by placing its cash and cash equivalents and short-term investments with high credit quality financial institutions.

Contractual Maturities of Investments

As of December 31, 2023, all of the Company's available-for-sale investments were due within one year or less.

Available-for-sale Investments

The following table summarizes the Company's available-for-sale securities by security type:

	As of December 31, 2023		
	Amortized Cost	**Unrealized Losses**	**Fair Value**
Cash equivalents:			
Money market funds	$ 34,741	$ —	$ 34,741
Total cash equivalents	$ 34,741	$ —	$ 34,741
Short-term investments:			
U.S. government and agency securities	$ 999	$ —	999
Total short-term investments	$ 999	$ —	$ 999
Total	$ 35,740	$ —	$ 35,740

	As of December 31, 2022		
	Amortized Cost	**Unrealized Losses**	**Fair Value**
Cash equivalents:			
Money market funds	$ 52,045	$ —	$ 52,045
Corporate debt securities	2,498	(1)	2,497
Non-U.S. debt securities	800	—	800
Total cash equivalents	$ 55,343	$ (1)	$ 55,342
Short-term investments:			
Commercial paper	$ 2,909	$ —	$ 2,909
U.S. government and agency securities	8,451	(8)	8,443
Total short-term investments	$ 11,360	$ (8)	$ 11,352
Total	$ 66,703	$ (9)	$ 66,694

The gross unrealized losses as of December 31, 2022 were due primarily to changes in market interest rates. The Company records an allowance for credit loss when a decline in investment market value is due to credit-related factors. When evaluating an investment for impairment, the Company reviews factors such as the severity of the impairment, changes in underlying credit ratings, forecasted recovery, the Company's intent to sell or the likelihood that it would be required to sell the investment before its anticipated recovery in market value and the probability that the scheduled cash payments will continue to be made. As of December 31, 2023, there were no material declines in the market value of available-for-sale investments due to credit-related factors.

As of December 31, 2023 and 2022, there were no material unrealized gains associated with the Company's available-for-sale investments.

5. Accrued Expenses

Accrued expenses are comprised of the following (in thousands):

	December 31, 2023	December 31, 2022
Compensation and related benefits	$ 3,472	$ 3,729
Clinical and contract manufacturing expenses	1,790	1,800
Other	596	671
Total accrued expenses	$ 5,858	$ 6,200

6. Leases

The Company has certain facility leases with non-cancellable terms ranging between two years 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 10%. 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 December 31, 2023 is 2.0 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 maturities of operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2023 are as follows (in thousands), excluding option renewals:

As of December 31, 2023:		
2024	$	332
2025		303
2026		17
Thereafter		—
Total lease payments		652
Less: Imputed interest		(67)
Total	$	585

Lease costs for operating leases were $0.3 million for each of the years ended December 31, 2023 and 2022.

7. Stock-Based Compensation and Employee Benefit Plans

Stock Options and Performance Stock Options

In 2012, Private Lumos adopted the 2012 Equity Incentive Plan ("2012 Plan"), and in 2016 it adopted the 2016 Stock Plan ("2016 Plan" and together with the 2012 Plan, the "Plans"). In connection with the Merger, all outstanding options under the Plans were assumed and such assumed options may be exercised to purchase common stock of the Company after the Merger. Subsequent to the Merger, the Plans were terminated as to future awards.

In connection with the Merger, the Company assumed NewLink's 2009 Equity Incentive Plan which was effective since July 2009 and was subsequently amended on May 9, 2019 (the "2019 Plan"). The 2019 Plan has a 10 year term from the Board adoption date of March 22, 2019 and on January 1 of each year through January 1, 2029, in accordance with an "evergreen provision", 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 Board, will be added to the shares reserved under the 2019 Plan. The 2019 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards and stock appreciation rights to officers, employees, members of the Board, advisors, and consultants to the Company. As of December 31, 2023, we had 712,026 shares available for grant under the 2019 Plan.

The table below summarizes the stock option activity, including options with market and performance conditions, for the year ended December 31, 2023:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	1,449,179	$ 10.43	6.9
Options granted	227,428	3.48	
Options exercised	—	—	
Options forfeited	(29,854)	8.61	
Options expired	(247,728)	12.87	
Outstanding and expected to vest at end of period	1,399,025	$ 8.91	6.8
Options exercisable at end of period	922,640	$ 9.52	6.0

The weighted-average assumptions used to value the stock options using the Black-Scholes option-pricing were as follows:

	Year Ended December 31,	
	2023	2022
Risk-free interest rate	3.38% to 4.06%	1.32% to 3.01%
Expected dividend yield	—%	0%
Expected volatility	97.9% to 98.8%	83.7% to 96.1%
Expected term (in years)	4.0 to 6.1	5.5 to 6.1
Weighted-average grant-date fair value per share	$2.57	$6.75

Restricted Stock Units

The table below summarizes the restricted stock units activity for the year ended December 31, 2023:

	Number of restricted shares	Weighted average grant date fair value
Unvested at beginning of period	69,794	$ 8
Granted	14,900	3
Vested	(27,564)	8
Forfeited	(4,700)	9
Unvested at end of period	52,430	$ 7

The following summarizes the weighted average fair value at the date of grant:

	Year Ended December 31,	
	2023	2022
Per grant of restricted stock unit	$ 3.45	$ 9.18

2010 Non-Employee Directors' Stock Award Plan

In connection with the Merger, the Company assumed NewLink's 2010 Non-Employee Directors' Stock Award Plan (the "Directors' Plan") which was effective on November 10, 2011. As of December 31, 2023, 5,624 shares remain available for grant under the Directors' Plan.

2010 Employee Stock Purchase Plan

In connection with the Merger, the Company assumed NewLink's 2010 Employee Stock Purchase Plan, as amended (the "2010 Purchase Plan"), which was effective on November 10, 2011. As of December 31, 2023, 35,946 shares remain available for issuance under the 2010 Purchase Plan. On July 22, 2021, the Board approved an amendment and restatement of the 2010 Purchase Plan (the "A&R ESPP"), and established a special offering period under the A&R ESPP beginning September 1, 2021 and lasting until June 30, 2023, subject to restart provisions as described within the A&R ESPP. The special offering period under the A&R ESPP was fully contingent upon stockholder approval of the A&R ESPP at the 2022 Annual Meeting of Stockholders. The A&R ESPP provided for an increase in the number of shares reserved for issuance under the A&R ESPP by 60,000 shares. On May 4, 2022, at the 2022 Annual Meeting of Stockholders, the A&R ESPP was approved. On June 30, 2022, December 30, 2022, and June 30, 2023, the restart provision was triggered, resulting in new offering periods. The current offering period is from July 1, 2023 through June 30, 2025.

Stock-Based Compensation Expense

Stock-based compensation expenses included in the Company's consolidated statements of operations for the year ended December 31, 2023 and 2022 were (in thousands):

	Year Ended December 31,	
	2023	**2022**
Research and development	$ 617	$ 661
General and administrative	1,705	1,659
Total	$ 2,322	$ 2,320

As of December 31, 2023, we had unrecognized compensation cost of $2.5 million and the weighted-average period over which it is expected to be recognized is 1.9 years.

Employee Benefit Plans

The Company sponsors a 401(k) plan that provides for a defined annual employer contribution. The Company's defined contribution was $0.4 million and $0.3 million for the years ended December 31, 2023 and 2022, respectively.

8. Long-Term Debt and Conversion to Royalty Obligation

In March 2005, NewLink entered into a $6.0 million forgivable loan agreement with the Iowa Department of Economic Development (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. This loan was converted into a royalty obligation under the terms of a settlement agreement entered into on March 26, 2012, with the Iowa Economic Development Authority, as successor in interest to the IDED. As no payments are expected in the next 12 months, the entire royalty obligation of $6.0 million, which the Company assumed in connection with the Merger, is classified as a long-term liability as of December 31, 2023.

9. Income Taxes

For the years ended December 31, 2023 and 2022, the Company recorded an income tax benefit of $29,000 and $13,000, respectively. The income tax benefit is as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Current tax benefit - state and local	$ 29	$ 13
Total income tax benefit	$ 29	$ 13

The Company had no deferred tax liabilities for each of the years ended December 31, 2023 and 2022. The tax effects of temporary differences that give rise to significant portions of deferred tax assets at December 31, 2023 and 2022 are presented below (in thousands):

	As of December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 39,043	$ 35,236
Federal research and development tax credits	42,949	39,190
Capitalized research and development	8,187	4,018
Stock-based compensation	603	678
Capital loss carryforwards	41,144	41,144
Accrued compensation	233	221
Leasehold improvements and equipment	1,125	1,205
Other	(4)	2
Gross deferred tax assets	133,280	121,694
Less: valuation allowance	(133,280)	(121,694)
Total deferred tax assets	$ —	$ —

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. 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, 2023 and 2022. The valuation allowance increased by $11.6 million and $8.2 million during the years ended December 31, 2023 and 2022, respectively.

Based on Section 382 ownership change analyses through March 18, 2020, as a result of the Merger, both historical NewLink and Private Lumos experienced Section 382 ownership changes on March 18, 2020. These ownership changes limit 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. Based on subsequent analyses, we did not experience a Section 382 ownership change from March 19, 2020 through December 31, 2022. As of December 31, 2023, the Company had federal operating loss carryforwards of approximately $156.9 million, federal capital loss carryforwards of approximately $164.6 million, and federal research credit carryforwards of approximately $42.9 million. Certain of the carryforwards expire in years 2024 through 2043, and certain of the carryforwards have an indefinite life.

A reconciliation of income taxes at the statutory federal income tax rate to net income tax benefit included in the accompanying consolidated statements of operations is set forth in the following table:

	Year Ended December 31,	
	2023	2022
U.S. federal income tax benefit at the statutory rate	(21.0) %	(21.0) %
State income taxes, net of federal taxes	(3.6)	(2.1)
Federal tax credits	(8.9)	(6.3)
Change in valuation allowance	34.0	26.3
Other	(0.6)	3.1
Effective income tax rate	(0.1) %	— %

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.

The Company had no reserve for uncertain tax positions as of December 31, 2023 and 2022 and no interest or penalties were recognized for the years ended December 31, 2023 and 2022. Tax years 2020 through 2022 remain open to examination by the major taxing jurisdictions in which the Company operates.

10. Stockholders' Equity

Common Stock

The Company's common stock trades on the Nasdaq under the symbol "LUMO." Our shareholders are entitled to one vote for each share of common stock held on all matters to be voted on by shareholders. We have 75,000,000 authorized common shares, par value of $0.01 per share. The holders of common stock are entitled to one vote per share on all matters to be voted upon by the Company stockholders.

On August 16, 2022, the Company announced that its board of directors had authorized a share repurchase program, under which the Company may purchase up to $3.0 million shares of its outstanding common stock. The Company repurchased an aggregate of 379,942 shares for approximately $1.3 million during the year ended December 31, 2023 and an aggregate of 137,526 shares for approximately $0.7 million during the year ended December 31, 2022. All such purchases were made through open-market transactions with shares effectively retired upon repurchase. On August 17, 2023, the Company terminated its share repurchase program.

On December 30, 2020, the Company entered into a Controlled Equity Offering[SM] Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as agent (the "Agent"), pursuant to which the Company may offer and sell from time to time through the Agent up to $50.0 million of shares of the Company's common stock, $0.01 par value (the "Shares"). The offering and sale of the Shares has been registered under the Securities Act of 1933, as amended (the "Securities Act"). Under the Sales Agreement, the Agent may sell the Shares by any method permitted by law and deemed to be an "at-the-market" offering as defined in Rule 415(a)(4) promulgated under the Securities Act, including sales made directly on or through the Nasdaq, on any other existing trading market for the Shares, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices and/or any other method permitted by law. The Company will notify the Agent of the number of Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Shares that may be sold in any one day and any minimum price below which sales may not be made. The Company will pay the Agent a commission of up to 3.0% of the gross sales price of the Shares sold through it under the Sales Agreement. In addition, the Company has agreed to reimburse certain expenses incurred by the Agent in connection with the offering. The Sales Agreement may be terminated by the Agent or the Company at any time upon notice to the other party, as set forth in the Sales Agreement, or by the Agent at any time in certain circumstances, including the occurrence of a material and adverse change in the Company's business or financial condition that makes it impractical or inadvisable to market the shares or to enforce contracts for the sale of the Shares. As of December 31, 2022, no shares had been issued under the Sales Agreement. During the year ended December 31, 2023, the Company sold an aggregate of 181,700 shares under the Sales Agreement, for net proceeds of approximately $0.7 million.

Preferred Stock

The Company's amended and restated certificate of incorporation authorizes the issuance of 5,000,000 shares of preferred stock, par value $0.01 per share. Our Board is empowered, without shareholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of common stock. As of December 31, 2023, the Company had no outstanding preferred stock.

11. 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) and the number of unexercised stock options and restricted stock units, which are common stock equivalents, that have been excluded from the diluted net loss calculation as their effect would have been anti-dilutive for all periods presented:

	Year Ended December 31,	
	2023	**2022**
Net loss	$ (34,034)	(31,062)
Weighted-average shares outstanding - Basic and diluted	8,145,155	8,373,821
Net loss per share - Basic and diluted	$ (4.18)	$ (3.71)
Anti-dilutive stock options	1,399,025	1,449,187
Anti-dilutive restricted stock units	52,430	69,794
Total anti-dilutive common stock equivalents excluded	1,451,455	1,518,981

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, as required by Rule 13a-15(b) of 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, 2023. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2023, 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, 2023 based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO Framework). As a result of this assessment, management concluded that, as of December 31, 2023, 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.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of 2023 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.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated herein by reference to the 2024 Proxy Statement, which will be filed with the SEC not later than 120 days subsequent to December 31, 2023.

Item 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference to the 2024 Proxy Statement, which will be filed with the SEC not later than 120 days subsequent to December 31, 2023.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated herein by reference to the 2024 Proxy Statement, which will be filed with the SEC not later than 120 days subsequent to December 31, 2023.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated herein by reference to the 2024 Proxy Statement, which will be filed with the SEC not later than 120 days subsequent to December 31, 2023.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated herein by reference to the 2024 Proxy Statement, which will be filed with the SEC not later than 120 days subsequent to December 31, 2023.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as a part of this report:

(1) Financial Statements: The consolidated financial statements and related notes, together with the report of KPMG LLP, Independent Registered Public Accounting Firm, appear in Part II, Item 8, Financial Statements and Supplementary Data, of this Annual Report.

(2) Financial Statement Schedules: All schedules for which provision is made in the applicable accounting regulations of the SEC are not required under the related instruction or are inapplicable and, therefore, have been omitted.

(3) Exhibits: The exhibits listed below on the Index to Exhibits are filed or incorporated by reference as part of this Annual Report.

INDEX TO EXHIBITS

Exhibit Number		Description	Incorporated By Reference			Filed Herewith
			Form	Filing Date	Number	
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	9/20/2019	2.1	
2.2		Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated November 19, 2019, by and among NewLink Genetics Corporation, Cyclone Merger Sub, Inc. and Lumos Pharma, Inc.	8-K	11/20/2019	2.1	
3.1		Amended and Restated Certificate of Incorporation filed on November 16, 2011, as amended	10-K	3/9/2021	3.1	
3.2		Amended and Restated Bylaws	8-K	9/30/2019	3.2	
4.1		Form of the Registrant's Common Stock Certificate	8-K	3/18/2020	4.1	
4.2		Description of Securities	10-K	3/9/2021	4.2	
10.1	†	Controlled Equity Offering℠ Sales Agreement, dated December 30, 2020, between the Registrant and Cantor Fitzgerald & Co.	8-K	12/30/2020	10.1	
10.2	†	PRV Transfer Agreement, dated as of July 27, 2020, by and between the Registrant and Merck, Sharp & Dohme Corp.	10-Q	8/14/2020	10.1	
10.3	†	License Agreement by and between Merck Sharp & Dohme Corp. and Ammonett Pharma LLC, effective as of October 22, 2013	8-K/A	5/29/2020	10.1	
10.4	†	Amendment No. 1 as of August 12, 2020 to Lumos Merck Agreement with Merck	10-Q	8/14/2020	10.2	
10.5	†	Asset Purchase Agreement by and among Lumos Pharma, Inc., Ammonett Pharma LLC, and each of certain individuals listed, effective July 26, 2018	8-K/A	5/29/2020	10.2	
10.6	*	Amended and Restated 2009 Equity Incentive Plan	S-1	12/21/2010	10.6	
10.7	*	Form of Stock Option Agreement under 2009 Equity Incentive Plan	S-1	12/21/2010	10.7	
10.8	*	Form of Stock Option Grant Notice under 2009 Equity Incentive Plan	S-1	12/21/2010	10.8	
10.9	*	Form of Restricted Stock Unit Award Agreement under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.6	
10.10	*	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	
10.11	*	Form of Restricted Stock Unit Grant Notice [Immediately Vested] under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.8	
10.12	*	2010 Employee Stock Purchase Plan	8-K	5/14/2013	10.2	
10.13	*	2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	11/8/2016	10.1	
10.14	*	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	
10.15	*	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	
10.16	*	Lumos Pharma, Inc. 2012 Equity Incentive Plan	8-K	3/18/2020	10.1	

10.17	*	2012 Equity Incentive Plan Form of Incentive Stock Option Agreement	8-K	3/18/2020	10.2	
10.18	*	Lumos Pharma, Inc. 2016 Equity Incentive Plan	8-K	3/18/2020	10.3	
10.19	*	2016 Form of Stock Option Agreement	8-K	3/18/2020	10.4	
10.20	*	Form of Indemnity Agreement by and between the Registrant and its directors and officers	10-K	3/9/2021	10.20	
10.21	*	Employment Agreement, dated as of March 27, 2020, by and between the Registrant and Richard Hawkins	8-K	4/2/2020	10.1	
10.22	*	Employment Agreement, dated as of March 27, 2020, by and between the Registrant and John McKew	8-K	4/2/2020	10.2	
10.25	*	Employment Agreement, dated September 30, 2019, by and between the Registrant and Lori Lawley	8-K	9/30/2019	10.5	
10.26	*	Employment Agreement, dated September 30, 2019, by and between the Registrant and Brad Powers	8-K	9/30/2019	10.6	
10.27	*	Employment Agreement, dated August 3, 2021, by and between the Registrant and David Karpf	10-Q	11/5/2021	10.1	
10.28	*	Amendment No. 1 to Employment Agreement, dated June 30, 2021, by and between the Registrant and Lori Lawley	10-Q	8/6/2021	10.1	
10.29	*	Amendment No. 1 to Employment Agreement, dated August 1, 2021, by and between the Registrant and John McKew	10-Q	8/6/2021	10.2	
21.1		Subsidiary Information				X
23.1		Consent of KPMG LLP, Independent Registered Public Accountants				X
24.1		Power of Attorney (included on signature page hereto)				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
97.1		Compensation Recovery Policy				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
104		Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				X

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 Lumos Pharma, Inc. 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.

‡ Filed herewith electronically.

* Indicates management contract or compensatory plan.

† Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

LUMOS PHARMA, INC.

By: /s/ Richard J. Hawkins
Richard J. Hawkins
Chief Executive Officer
(Principal Executive Officer)
Date: March 7, 2024

By: /s/ Lori D. Lawley
Lori D. Lawley
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)
Date: March 7, 2024

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Richard J. Hawkins and Lori D. Lawley, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution, for him or her and in his or her 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 or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or his or her 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 and on the dates indicated:

Name	Title	Date
/s/ Richard J. Hawkins Richard J. Hawkins	Chief Executive Officer (Principal Executive Officer)	March 7, 2024
/s/ Lori D. Lawley Lori D. Lawley	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 7, 2024
/s/ Thomas A. Raffin Thomas A. Raffin	Director	March 7, 2024
/s/ Joe McCracken, DVM, MS Joe McCracken, DVM, MS	Director	March 7, 2024
/s/ Lota Zoth Lota Zoth	Director	March 7, 2024
/s/ Chad A. Johnson, JD Chad A. Johnson, JD	Director	March 7, 2024
/s/ An van Es-Johansson An van Es-Johansson	Director	March 7, 2024
/s/ Kevin Lalande Kevin Lalande	Director	March 7, 2024

Exhibit 21.1

SUBSIDIARIES OF LUMOS PHARMA, INC.

Subsidiary	Jurisdiction of Incorporation
NewLink International	Cayman Islands
BlueLink Pharmaceuticals, Inc	Delaware
BioProtection Systems Corporation	Delaware
Lumos Pharma Sub, Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-266966, 333-239137, and 333-240149) on Form S-3 and (Nos. 333-178032, 333-184880, 333-186020, 333-203350, 333-234644, 333-237590, and 333-259136) on Form S-8 of our report dated March 7, 2024, with respect to the consolidated financial statements of Lumos Pharma, Inc.

/s/ KPMG LLP

Austin, Texas
March 7, 2024

EXHIBIT 31.1

CERTIFICATION

I, Richard J. Hawkins, certify that:

1. I have reviewed this Form 10-K of Lumos Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2024

By: /s/ Richard J. Hawkins
Richard J. Hawkins
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Lori Lawley, certify that:

1. I have reviewed this Form 10-K of Lumos Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2024

By: /s/ Lori Lawley
Lori Lawley
Chief Financial Officer and Secretary
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION

Pursuant to the requirements set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Richard J. Hawkins, Chief Executive Officer of Lumos Pharma, Inc. (the "Company"), and Lori Lawley, Chief Financial Officer and Secretary of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of March 7, 2024.

By: /s/ Richard J. Hawkins
Richard J. Hawkins
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Lori Lawley
Lori Lawley
Chief Financial Officer and Secretary
(Principal Financial Officer)

A signed original of this written statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its Staff upon request. This certification "accompanies" the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company 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 the Form 10-K), irrespective of any general incorporation language contained in such filing