UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K/A

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 17, 2020

LUMOS PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35342**	**42-1491350**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

4200 Marathon Blvd., Suite 200
Austin, Texas 78756
(Address of principal executive offices)

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

NewLink Genetics Corporation
2503 South Loop Drive
Ames, Iowa 50010
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2 of this chapter) ☐

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. ☐

Explanatory Note

On March 18, 2020, Lumos Pharma, Inc., formerly known as "NewLink Genetics Corporation," ("**Lumos**" or the "**Company**"), filed a Current Report on Form 8-K (the "**Original Form 8-K**"), reporting, among other items, that on March 18, 2020, the Company completed its business combination (the "**Merger**") with what was then known as Lumos Pharma, Inc., and has since been renamed "Lumos Pharma Sub, Inc." ("**Private Lumos**"). This Current Report on Form 8-K/A amends the Original Form 8-K to provide (i) certain voluntary disclosure concerning the business and financial condition of Private Lumos, as permitted by Item 8.01; (ii) the historical audited financial statements of Private Lumos as of and for the years ended December 31, 2018 and 2019, as required by Item 9.01(a) of Form 8-K; and (iii) the unaudited pro forma condensed combined balance sheet as of the year ended December 31, 2019 and unaudited combined condensed statement of operations for the year ended December 31, 2019, as required by Item 9.01(b) of Form 8-K. Such financial information was excluded from the Original Form 8-K in reliance on the instructions to such items.

Item 8.01. Other Events.

In connection with the Merger and related transactions described in the Original Form 8-K and this Current Report on Form 8-K/A, the Company provides the following information related to the Company set forth in this Item 8.01.

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

The information in Item 8.01 of this Current Report on Form 8-K/A, particularly in the sections entitled "Lumos Business," and "Lumos Management's Discussion and Analysis of Financial Condition and Results of Operations," and the information incorporated herein by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are based on current expectations and beliefs and involve numerous risks and uncertainties that could cause actual results to differ materially from expectations. These forward-looking statements should not be relied upon as predictions of future events as we cannot assure you that the events or circumstances reflected in these statements will be achieved or will occur. 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. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements.

If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, our results could differ materially from the forward-looking statements in this report. All forward-looking statements in this report are current only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events.

FORMATION

The Company was incorporated in the State of Delaware on June 4, 1999 under the name “NewLink Genetics Corporation.” On March 18, 2020, NewLink merged Cyclone Merger Sub, Inc., a wholly-owned subsidiary of NewLink, with what was then known as Lumos Pharma, Inc., and has since been renamed “Lumos Pharma Sub, Inc.”, and changed the name “NewLink Genetics Corporation” to “Lumos Pharma, Inc.” Unless otherwise indicated, references to “Lumos” or the “Company” prior to the Merger refer to Private Lumos, and such references following the Merger, to Lumos Pharma, Inc., formerly known as NewLink Genetics Corporation. References to “NewLink” refer to NewLink Genetics Corporation prior to the Merger. Under the terms of the Merger, Private Lumos stockholders received an aggregate of 4,146,398 shares of NewLink common stock, at an exchange rate of (i) 0.1308319305 shares of common stock in exchange for each share of Private Lumos common stock outstanding immediately prior to the Merger, (ii) 0.0873621142 shares of NewLink common stock in exchange for each share of Private Lumos Series A Preferred Stock outstanding immediately prior to the Merger, and (iii) 0.1996348626 shares of NewLink common stock in exchange for each share of Private Lumos Series B Preferred Stock outstanding immediately prior to the Merger. Immediately following the Merger, the former Private Lumos stockholders beneficially owned approximately 50% of the shares of the Company and the former NewLink stockholders beneficially owned approximately 50% of the shares of the Company. For accounting purposes, Private Lumos is considered to have acquired NewLink in the Merger.

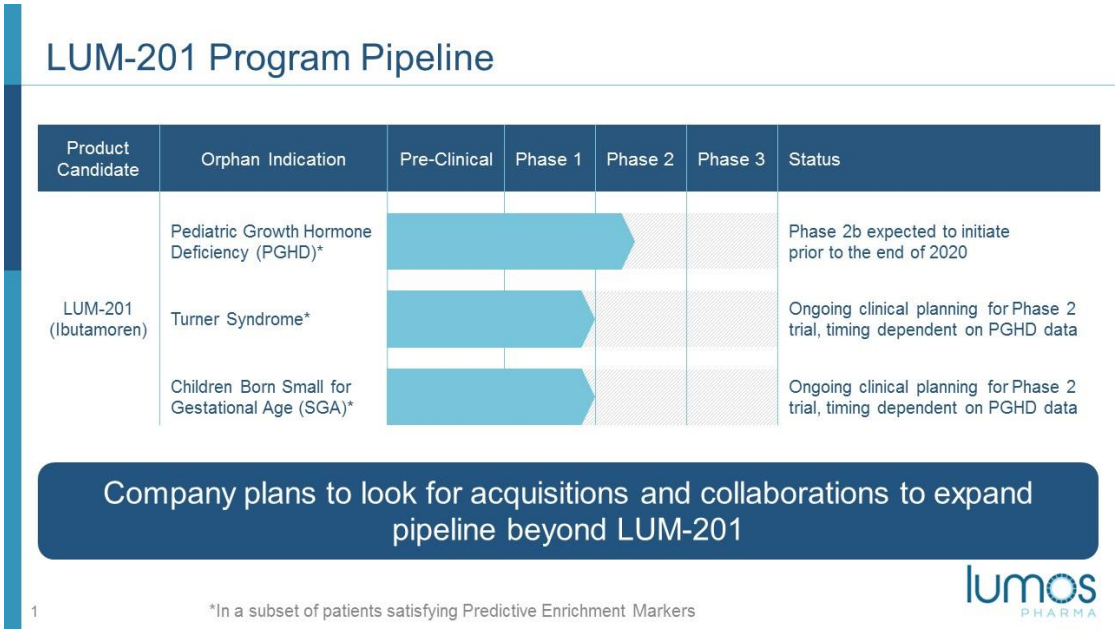
LUMOS BUSINESS

Overview

Lumos is a clinical-stage biopharmaceutical company focused on the identification, acquisition and in-license, development, and commercialization of novel products for the treatment of rare diseases. Lumos’ mission is to develop new therapies for people with rare diseases, prioritizing its focus where the medical need is high, and the pathophysiology is clear.

LUM-201 Growth Hormone Secretagogue

The current Lumos pipeline is focused on the development of an orally administered small molecule, the growth hormone (“**GH**”) secretagogue ibutamoren (“**LUM-201**”) for rare endocrine disorders where injectable recombinant human growth hormone ("**rhGH**") is currently approved. A secretagogue is a substance that stimulates the secretion or release of another substance. LUM-201 stimulates the release of GH and is referred to as a GH secretagogue. The current targeted indications for LUM-201 are Pediatric Growth Hormone Deficiency ("**PGHD**"), Turner Syndrome and Children Born Small for Gestational Age (“**SGA**”), in each case in a certain subset of affected patients. Lumos is planning to initiate a clinical development program to study the effects of LUM-201 in PGHD prior to the end of 2020 with a Phase 2b clinical trial (the "**Phase 2b Trial**"). The coronavirus pandemic has caused pervasive interruptions to clinical trials industrywide. Facing similar near-term impediments, the Company has experienced some delays related to the pandemic and may experience further delays should the significant pandemic related disruptions persist. Depending on the outcome of data developed in the Phase 2b Trial and the timing of such data, Lumos plans to conduct Phase 2 clinical trials to study the effects of LUM-201 for Turner Syndrome and SGA in certain subsets of affected patients. The graphic below depicts these indications with their respective development status.



LUM-201 stimulates GH via the GH secretagogue receptor, also known as the ghrelin receptor ("**GHSR1a**"), thus providing a differentiated mechanism of action intended to treat some rare endocrine disorders (involving a deficiency of GH) by increasing the amplitude of endogenous, pulsatile GH secretion. LUM-201's stimulatory effect is regulated by insulin-like growth factor 1 ("**IGF-1**") feedback, hence potentially protecting against hyperstimulation of GH. LUM-201 has been observed to stimulate endogenous GH secretion in patients who have a functional but reduced hypothalamic pituitary GH axis. LUM-201 is a tablet formulation that is administered orally once daily and if proven safe and effective may provide a new therapeutic approach to the 35-year old standard of care (subcutaneous injectable rhGH) for treating rare endocrine disorders associated with GH deficiencies.

LUM-201 for the Treatment of a Subset of PGHD Patients

Lumos is initially developing LUM-201 for a subset of patients with PGHD. PGHD is a rare endocrine disorder occurring in approximately one in 3,500 persons aged birth to 17 years. Causes of PGHD can be: congenital (children are born with the condition), acquired (brain tumor, head injuries or other causes), iatrogenic (induced by medical treatment), or idiopathic (of unknown cause). Children with untreated PGHD will have significant growth failure (potential adult heights significantly less than five feet and may have abnormal body composition with decreased bone mineralization, decreased lean body mass and increased fat mass).

The main therapeutic goal in PGHD is to restore growth, enabling short children to achieve normal height and prevent complications that could involve metabolic abnormalities, cognitive deficiencies and reduced quality of life. Current treatment of PGHD is limited to daily subcutaneous injections of rhGH with a treatment cycle lasting up to an average of seven years. Poor compliance in daily rhGH injections for an average seven-year treatment regime results in an adverse impact on overall health efficacy.

LUM-201 is intended to provide an oral treatment to stimulate the release of endogenous GH in PGHD patients who have a functional but reduced hypothalamic pituitary GH axis and are expected to respond to LUM-201. Lumos believes this group represents 50% to 60% of PGHD patients. Lumos is planning to initiate a clinical development program to study the effects of LUM-201 in PGHD by the end of 2020 with a Phase 2b Trial. Lumos has received a Study May Proceed letter from the U.S. Food and Drug Administration (the "**FDA**") after their review of Lumos' study protocol. As trial initiation is currently delayed by the COVID-19 pandemic, Lumos is evaluating whether there is opportunity within the proposed Phase 2b Trial to address additional FDA comments that could increase Phase 3 registration readiness. The submitted trial is a randomized study testing 3 doses of LUM-201 in a parallel enrollment approach versus the current standard dose of injectable rhGH with the twin goals of dose selection and refinement of patient selection for Phase 3.

Potential Expansion of LUM-201 into Additional Endocrine Indications

Lumos is also in the planning stages for developing LUM-201 for patients with Turner Syndrome. Turner Syndrome is a sex-linked developmental disorder that affects females only (one normal x chromosome, and the other x chromosome is either missing or structurally changed). It causes growth failure that begins before birth and continues into infancy and childhood, where it can be accentuated by the absence of puberty. If left untreated, girls with Turner Syndrome will usually achieve an average adult height that is significantly shorter than their peers.

Lumos is also in the planning stages for developing LUM-201 for the indication of SGA. SGA is a child born with birth weight and/or length under two standard deviations ("**SDS**") for the gestational age and sex of the population. Approximately five percent of all newborn children are SGA and a spectrum of factors are found to be causative: maternal, placental, fetal, metabolic, and genetic. In the newborn period, SGA children are at greater risk of life-threatening conditions such as: hypoglycemia, hypercoagulability, necrotic enterocolitis, direct hyperbilirubinemia, and hypotension. Approximately 10% of SGA children do not achieve catch-up growth and remain short (≥-2 SDS) into adulthood.

Lumos acquired LUM-201 from Ammonett Pharma LLC ("**Ammonett**") in July 2018. LUM-201 received the 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. Other patent applications are pending in multiple jurisdictions.

Since its inception, Private Lumos' operations have focused on organizing and staffing, business planning, raising capital, acquiring its technology and assets, and conducting preclinical and clinical development of its product candidates. Private Lumos has devoted substantial effort and resources to acquiring its current product candidate, LUM-201, as well as its previous product candidate, a preclinical compound cyclocreatine ("**LUM-001**"), which it ceased developing in 2019. Private Lumos acquired LUM-201 through its acquisition of substantially all of the assets related to LUM-201 from Ammonett which had licensed LUM-201 in October 2013 from Merck, Sharpe and Dohme Corp. ("**Merck**"). Private Lumos has not generated any revenue from product sales. Prior to the Merger, Private Lumos funded its operations primarily through the sale and issuance of preferred stock, as well as through in-kind support pursuant to a collaborative research and development agreement with the National Institutes of Health (the "**NIH**") from 2012 to February 2020.

Lumos History

Private Lumos was founded in 2011 by its President, Chief Executive Officer, and Chairman Richard J. Hawkins, who is the co-founder of Sensus, a company that developed Somavert® for the rare endocrine disease, acromegaly, that was later sold to Pharmacia Upjohn which was later sold to Pfizer. Mr. Hawkins is also the co-founder of Pharmaco, a contract research organization ("**CRO**") that merged with Pharmaceutical Product Development LLC, and the co-founder of Covance Biotechnology Services, a biotech services company that was later sold to Akzo Nobel.

Lumos has assembled an experienced team with extensive drug development and commercialization capabilities, particularly in the orphan drug area. Mr. Hawkins and the current team at Lumos have been previously involved, at other companies, in the development and/or commercialization of many therapies approved or in development for rare endocrine, neurological and metabolic genetic diseases, including Somavert®, Norditropin®, Increlex®, Abilify®, Carbaglu® and Orfadin®. Moreover, the management team also has strong experience in raising capital for drug development companies, including Lumos, Sensus, and aTyr.

Lumos' focus, as a rare disease drug developer, started with the license from the University of Cincinnati of LUM-001 a small molecule for the indication of Creatine Transporter Deficiency ("**CTD**"). CTD is an x-linked pediatric neurodevelopmental disorder, due to mutations of the SLC6A8 gene, that inhibits the transport of sufficient levels of creatine to the brain. Extensive preclinical development was performed by Lumos on LUM-001, as well as the initiation and completion of a Phase 1 trial in healthy volunteers. Lumos determined in April 2019 that the clinical path forward for LUM-001 was not viable due to safety signals in the non-clinical juvenile and chronic toxicology studies running concurrently with the Phase 1 clinical trial observed for the compound and the program was discontinued.

Lumos acquired LUM-201 from Ammonett in July 2018. See "- APA, Lumos Merck Agreement and Other Agreements" for additional information. LUM-201 received the ODD in the United States and the European Union for GHD in 2017, which is a necessary step in being granted market exclusivity for defined time periods in each of these markets upon approval. Lumos holds the United States patent 9763919 "Detecting and Treating Growth Hormone Deficiency," which has been issued with an expiration in 2036 and could provide extended market protections beyond the United States ODD exclusivity period. Lumos is actively seeking similar patent protection in multiple jurisdictions worldwide. In addition, Lumos has filed a United States and Patent Cooperation Treaty ("**PCT**") application for LUM-201 in the treatment of Non-Alcoholic Fatty Liver Disease ("**NAFLD**"). See "- Intellectual Property" for more details.

Lumos does not intend to pursue further internal development of the existing pipeline that NewLink had developed prior to the Merger, but will continue to evaluate such pre-Merger pipeline and may seek to identify potential partnerships and out-licensing opportunities.

In November 2014, NewLink entered into an exclusive, worldwide license and collaboration agreement with Merck (the "**NewLink Merck Agreement**") to develop and potentially commercialize NewLink's rVSVΔG-ZEBOV-GP vaccine product candidate and other aspects of NewLink's vaccine technology. 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, which was developed under the NewLink Merck Agreement. On January 3, 2020, Merck notified NewLink that they had been issued a priority review voucher ("**PRV**"). Under the terms of the NewLink Merck Agreement, on February 4, 2020, Merck assigned all of its rights and interests in connection with the PRV to NewLink.

As a result of such arrangements, Lumos is entitled to 60% of the value of the PRV obtained through sale, transfer or other disposition of the PRV. Lumos also has the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is successfully commercialized by Merck. However, Lumos believes 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 Lumos does not expect to receive material royalty payments from Merck in the foreseeable future.

Lumos Rare Disease Focus

Patient-focused drug development for rare diseases is the foundational focal point at Lumos. Rare disease patients and their caretakers inspire Lumos to learn as much as it can to persevere and continue to advance the development of potential therapies to treat rare diseases. For this reason, Lumos is committed to developing these therapies with the utmost urgency and care for these patients.

Lumos strives to build a rare disease company that is better and smarter about advancing product candidates through approval by engaging, early and often, the patient's perspective during the continuum of the drug development process. Lumos is dedicated to promoting a strong patient-centric philosophy among its partners and stakeholders. Lumos is grateful and honored to initiate and work on collaborative patient-focused projects such as increasing disease awareness, enabling better diagnostic modalities and access, and providing education and services to support patient and healthcare communities.

Lumos' Strategy

Lumos' strategy is to identify, acquire, develop, and commercialize novel products for the treatment of rare diseases on a global level, prioritizing direct commercialization in selected markets, beginning with the United States and seeking partnerships/licensing in other markets. The critical components of Lumos' business strategy include the following:

- focus on rare diseases with limited or no treatment options;
- focus on diseases and therapies with clear pathophysiology and mechanisms of action;
- leverage Lumos' experience and relationships to in-license promising product candidates from academic institutions, rare disease patient foundations, and/or derived from partnerships with other pharmaceutical companies;
- focus on creative, adaptive and rapid clinical and regulatory execution; and
- where possible, seek to retain global or broad commercialization rights to product candidates to maximize long-term value.

Driven by a sense of commitment to rare disease patients, their families, and the rare disease community, the goal of Lumos is to be a leading rare disease drug company.

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

Potential Market Opportunity

In the United States, approximately one in 3,500 children are born with PGHD. Children with PGHD are characterized by short stature, metabolic abnormalities, cognitive deficiencies, and poor quality of life. The current standard of care for PGHD is daily subcutaneous injections of rhGH, which dates back to 1985, and with donor-sourced GH since the 1950s. The worldwide sales of rhGH for PGHD were estimated to reach $1.12 billion in 2016 in the major markets, with such sales consisting of 65.2% in the United States, 20.6% in Japan, and 14.2% in the aggregate for the European markets of France, Germany, Italy, Spain, and the United Kingdom.

GH-deficient children who are fully in adherence with their daily treatment regimen may achieve a height in adulthood that is comparable to that of their family members and national norms. Despite the demonstrated benefits of rhGH therapy, compliance continues to be a challenge, as patients treated with daily rhGH typically receive thousands of injections over the course of many years. For caregivers of young children and teenagers who likely have had to endure daily injections of rhGH for many years, the problem of needle fatigue - missing injections because of the pain, bruising or other effects of daily treatment - remains an important reason for noncompliance with daily treatment.

There are various approaches by the pharmaceutical industry to develop rhGH products to reduce the patient burden of daily injections and increase patient compliance with the dosing regimen, including longer-acting GH treatments that would require less frequent injections. Lumos believes that an oral treatment may help a subset of PGHD patients to achieve better treatment results through better treatment compliance than is typical for the current standard of care.

If approved, LUM-201 will not be an appropriate treatment for all PGHD patients. Only patients with a demonstrated partially functioning hypothalamic-pituitary growth hormone HP-GH axis are likely to be good candidates for treatment with LUM-201. Lumos believes, based on data generated to date, that the proportion who fit such criteria is approximately 50% to 60% of all PGHD subjects. See "- Lumos' Product Candidate - LUM-201 addressable PGHD population" and "- Post-hoc analysis and using a predictive enrichment marker strategy to select appropriate patients" for additional information regarding LUM-201's mechanism of action and other data related to the addressable PGHD population for LUM-201.

In addition to PGHD, there are multiple other indications for which treatment with rhGH has been approved by the FDA. Lumos intends to investigate the safety and efficacy of LUM-201 in some of these other indications, subject to corporate prioritization and funding resources. Depending on the outcomes of its Phase 2b Trial, Lumos is planning for Phase 2 trials to investigate LUM-201's safety and efficacy for subsets of patients with Turner Syndrome and SGA.

Lumos' Product Candidate

LUM-201 for the treatment of a subset of PGHD patients

Background

GHD in children and adults is the consequence of low or absent secretion of GH from the pituitary gland. The numerous causes include neoplasia, trauma, inflammation, surgery and/or irradiation of the central nervous system, and genetic causes.

Children with untreated GHD will have significant growth failure with attainment of adult heights significantly less than five feet in many cases. In addition, they may have abnormal body composition with decreased bone mineralization, decreased lean body mass, and increased fat mass. Characteristics of GHD children include height below the 2.3 percentile of the normal range for age and gender, attenuated height velocity, and delayed bone maturation.

GH is an anabolic hormone synthesized, stored in, and secreted from somatotrophs of the anterior pituitary gland in response to chemical modulators from the hypothalamus and stomach. Upon release, GH acts on growth hormone receptors in multiple tissues and alone, or in concert with its downstream effectors, regulates diverse physiological processes. GH has been shown to directly stimulate protein synthesis, cellular proliferation and differentiation, including proliferation of bone chondrocytes that lead to linear growth. GH also impacts carbohydrate and lipid metabolism, mediating a net inhibition of glucose uptake and glycolysis, an increase in free fatty acids, and a decrease in urinary nitrogen excretion.

Secretion of GH is under strict and complex hormonal homeostatic control with growth hormone releasing hormone ("**GHRH**" or "**GRF**") and ghrelin as the most significant stimulators of its production and somatostatin ("**SST**") and IGF-1 exerting inhibitory action. At the level of the hypothalamus, GHRH and SST are released into the portal system to exert positive and negative effects, respectively. The secretion of GHRH and SST are modulated by neurotransmitters whose concentrations vary in response to a number of metabolic and chemical factors. Once GH is released, it stimulates release of IGF-1 into the circulation, primarily from the liver, and this effector in turn exerts negative feedback at the level of both the pituitary and the hypothalamus to limit GH release. GH also limits itself by stimulating secretion of SST from the hypothalamus. IGF-1 is critical to the actions of GH in that it acts in synergy with GH to promote linear growth in children and in the control of metabolism and body-mass composition in adults. IGF-1 is regulated through its own complex feedback mechanisms, involving GH and IGF-1 binding protein complexes. Finally, ghrelin produced in the stomach stimulates GH release. The ghrelin receptor, also known as the growth hormone secretagogue receptor GHSR1a, is expressed in the hypothalamus and pituitary, amongst other tissues. Ghrelin, LUM-201 and other GH secretagogues act on GHSR1a specifically in the anterior pituitary and hypothalamus to stimulate the ultradian release of GH.

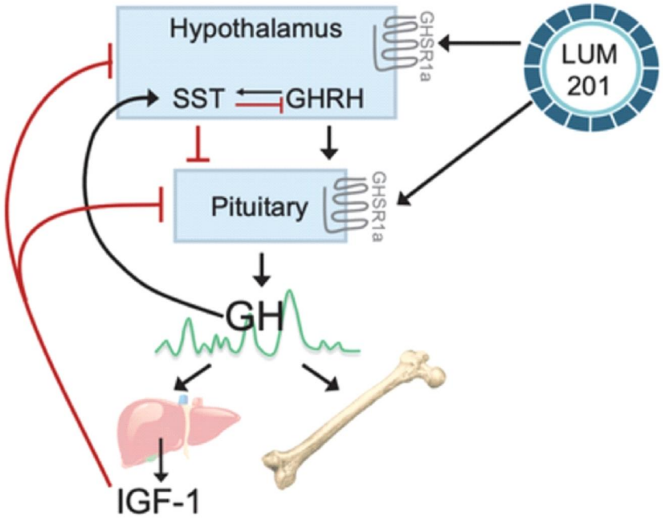
Current approved therapeutics and potential treatments

Current treatment of GHD children is limited to daily subcutaneous injections of rhGH. Daily administration of rhGH to prepubertal children with GHD does not mimic the daily pulsatile pattern of GH secretion, but nevertheless results in mean first year height velocities of 8.5 to 12 cm/yr, an improvement of 4 to 6 cm/yr over a patients previous six months of growth. Several patient pre-treatment characteristics have been found to correlate with higher first year velocities. First year height velocities are increased in younger patients, in those with greater initial height deficits and in those with more severe GHD (low stimulated GH response and/or low IGF-1 standard deviation scores). Treatment is required for an average of approximately seven years, but in the cases of congenital GHD may persist throughout life. Augmenting circulating GH levels with exogenous daily or weekly injections of GH forms (several of such weekly, or long-acting rhGH forms are currently in clinical development), has been proven to be an effective strategy for treating GHD in children.

Preclinical data supporting LUM-201's use in PGHD

Merck originally developed LUM-201 as a GH secretagogue that selectively acts on GHSR1a specifically in the anterior pituitary and hypothalamus to stimulate the ultradian release of GH. LUM-201 has demonstrated stimulatory GH responses following oral administration in mice, rats, dogs, pigs, and humans. The mechanism of action of LUM-201 is illustrated in Figure 1 below.

Figure 1: Mechanism of action of LUM-201

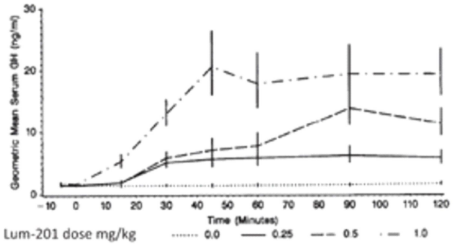


SST = somatostatin
IGF-1 = insulin-like growth factor-1
GHRH = growth hormone-releasing hormone
GHSR1a = GH secretagogue receptor 1a

GHSR1a activation via LUM-201 binding induces GH release, as demonstrated *in vitro* in rat pituicytes (LUM-201 EC_{50} 1.3 nM). In addition, the treatment of pituicytes with LUM-201 augments the effect of GHRH on GH secretion, as the two compounds synergistically stimulated GH release from rat pituitary cells, demonstrating distinct mechanisms of action.

Non-clinical evidence of the ability of LUM-201 to stimulate GH release is provided with the following example. In a crossover, randomized trial in eight fasting dogs, single doses of placebo or LUM-201 (0.25, 0.50, and 1 mg/kg) were administered orally with a seven-day interval between doses. Treatment with LUM-201 resulted in statistically significant, dose-dependent increases in both mean peak GH (C_{max}) and mean AUC, as shown in Figure 2 below. Mean GH C_{max} occurred 90 minutes (0.25 and 0.5 mg/kg) and 45 minutes (1.0 mg/kg) post-dose, with the GH levels remaining high at two hours post dose.

Figure 2: Geometric mean (±SEM) serum GH levels after single oral administration of LUM-201 in dogs



A comprehensive suite of pharmacology, pharmacokinetics and toxicology studies was conducted *in vitro* and *in vivo* in multiple, relevant non-clinical species. Potential drug-drug interactions were also evaluated *in vitro* in studies aligned with current regulatory guidance. Non-clinical testing focused mainly on daily oral administration of LUM-201, consistent with the intended clinical dose frequency and route. The toxicology studies completed by Merck with LUM-201 include acute, chronic, juvenile, developmental and reproductive, and carcinogenicity studies along with safety pharmacology studies. The results of these studies support the proposed clinical development plan.

Prior clinical experience with LUM-201 in adults

Merck's prior clinical experience with LUM-201 in adults consists of various single and multiple oral-dose trials in healthy young adult, diseased adults, GH-deficient adults, and elderly volunteers and patients conducted by Merck over a 13-year window that ended in 2006. Over 1,000 adult (including elderly) patients received at least one dose of LUM-201 at doses ranging from one to 200 mg. In these trials, LUM-201 was administered in tablet form. Approximately 500 subjects have received LUM-201 25 mg daily for at least six months. Over 200 subjects have been treated for as long as 12 months.

In a healthy elderly population given 25 mg per day of LUM-201, a sustained increase in circulating growth hormone levels and IGF-1 was observed. Both GH and IGF-1 geometric mean data show an increase from baseline at both six and 12 months of treatment as depicted in Figure 3 shown below. Additionally, a representative 24 hour GH release profile showed the LUM-201 induced increases in GH pulses compared to that patient's own baseline as depicted in Figure 4 shown below. Since GH release attenuates with age, healthy elderly people are growth hormone deficient compared to their younger healthy counterparts and can serve as a model for how growth hormone deficient children may respond to LUM-201.

Figure 3: Growth hormone and IGF-1 levels at baseline and at six and 12 months in a healthy elderly population treated with 25 mg per day of LUM-201

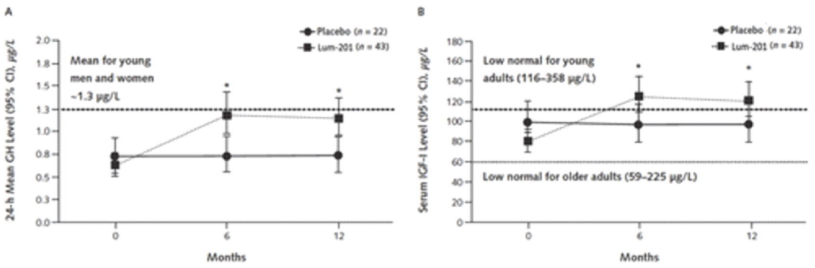
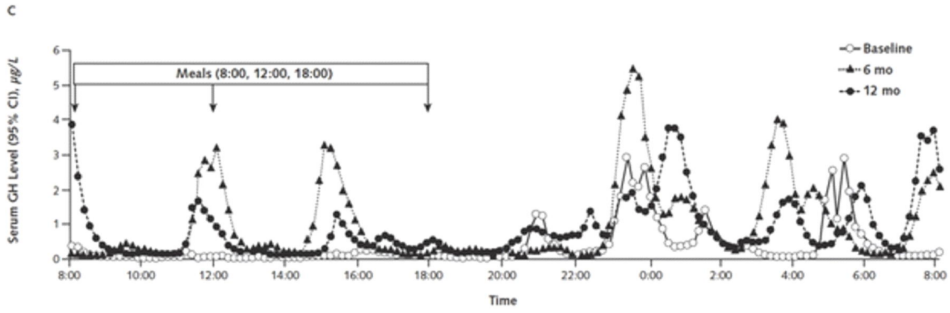


Figure 4: Representative 24 hour GH profile at baseline and at six and 12 months in a healthy elderly population treated with 25 mg per day of LUM-201



Prior clinical experience with LUM-201 in PGHD

Merck's prior clinical experience with LUM-201 in children occurred from 1996 to 1998 and consisted of three oral-dose trials in GHD children. A total of 204 previously diagnosed GHD children were enrolled into clinical trials and 157 children (67 of which were treatment naïve and 90 of which were previously rhGH treated subjects) received LUM-201 0.1 to 0.8 mg/kg administered daily as a liquid formulation for at least one week; 75 children were on therapy for at least six months. At the doses tested previously in three studies on LUM-201 completed by Merck in the 1990s, LUM-201 was generally well-tolerated in children with the most common reported adverse events encompassing digestive systems events, including appetite increase. Mild elevations in liver enzymes without accompanying changes in bilirubin were also reported.

The first trial was a double-blind, placebo-controlled, sequential, rising-dose trial of the safety, tolerability, biologic response, and plasma drug concentration profile of single and multiple (up to eight days) oral doses of LUM-201 administered in PGHD subjects. The second trial was a double-blind, placebo-controlled, dose-range finding trial in naïve-to-treatment PGHD subjects to explore safety and efficacy in a six-month treatment paradigm with a safety extension. The final PGHD trial was a randomized dose-range finding, parallel group trial in PGHD subjects previously treated with rhGH that evaluated safety and efficacy in a 12-month treatment paradigm compared to a rhGH treated cohort. The first trial was completed successfully and showed that, for a subset of PGHD patients, there were increases of both serum GH and IGF-1 after LUM-201 administration. Both efficacy trials were terminated prior to completion based on a preliminary efficacy analysis of the PGHD subjects previously treated with rhGH. There was a change in formulation midway through the second, naïve-to-treatment trial (months six to 12) and during the entire course of the third, previously rhGH-treated trial. The change in formulation lowered the bioavailability by 30% to 40% and thus the exposure of LUM-201 and may have been a confounding factor when analyzing efficacy data.

Post-hoc analysis and using a predictive enrichment marker strategy to select appropriate patients

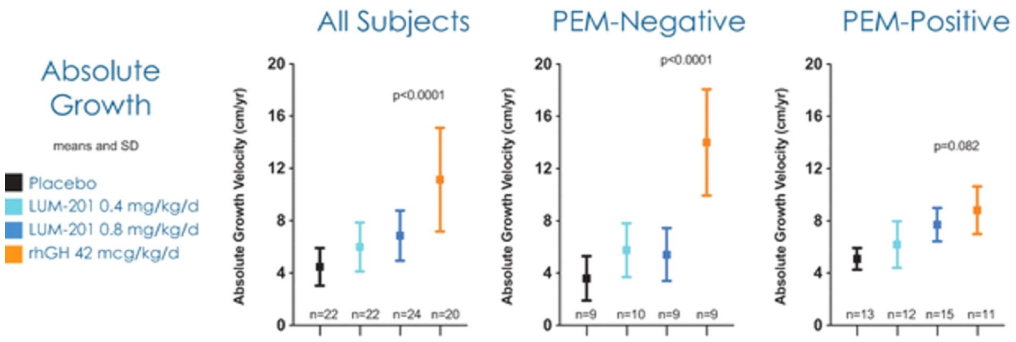
The use of predictive enrichment markers was examined in a post hoc analysis of the first six months of data from the naïve-to-treatment trial described above. An analysis of height velocity responses from months one to six of treatment with LUM-201 compared to rhGH treatment identified two distinct populations:

1. Subjects who are unable to secrete growth hormone and have a low potential for growth with LUM-201 versus rhGH treatment, and are defined by baseline serum IGF-1 ≤ 30 ng/ml and/or peak serum GH level of < 5 ng/ml in response to a single oral dose of 0.8 mg/kg LUM-201; **these children are defined as Predictive Enrichment Marker - Negative ("PEM-Negative")**; and

2. Subjects who can secrete some, but insufficient, GH are expected to have an equivalent potential for growth with LUM-201 versus rhGH treatment, and are defined by baseline serum IGF-1 > 30 ng/ml and peak serum GH level ≥ 5 ng/ml in response to a single oral dose of 0.8 mg/kg LUM-201; **these children are defined as Predictive Enrichment Marker - Positive ("PEM-Positive")**.

Children treated with LUM-201 grew less well than those treated with rhGH when all children were considered together (Figure 5 left graph, all subjects). Notably, when only the PEM-Positive children are considered (Figure 5 right graph), the growth in response to 0.8 mg/kg LUM-201 was enhanced and growth due to rhGH treatment was reduced, when compared to all children.

Figure 5: Mean height velocity after treatment with placebo, rhGH or LUM-201 for six months in all subjects and in subjects identified as having lower growth potential (PEM-Negative) or having similar growth potential (PEM-Positive) in response to LUM-201 compared to rhGH



This dichotomy of patient response reflects the biology that LUM-201 can reactivate a reduced, but intact, hypothalamic pituitary GH axis and potentially restore growth in PEM-Positive patients. LUM-201 may have similar growth potential to rhGH in this set of patients. To clarify, in the PEM-Negative children (Figure 5 middle panel) with an axis that is not able to respond to LUM-201, growth in response to treatment with LUM-201 at either administered dose is statistically less than rhGH (t-test $p<0.0001$) and therefore rhGH is the preferred treatment. This is also reflected in the left panel of Figure 5, where the inclusion of the PEM-Negative patients who cannot respond to LUM-201 in the overall analysis of all subjects creates a negative confounding effect such that patients treated with rhGH had a growth velocity of 11.14 cm/yr, statistically greater than the growth velocity in the entire cohort of patients treated with 0.8 mg/kg LUM-201, of 6.85 cm/yr (t-test $p<0.0001$). However, in the PEM-Positive children whom Lumos believes have the potential to respond to LUM-201, the growth velocity was not statistically different between rhGH (8.81 cm/yr) and 0.8 mg/kg of LUM-201 (7.71 cm/yr) using a t-test ($p = 0.082$, Figure 5 right graph). This p-value is greater than the scientific standard of 0.05, commonly used in scientific evaluation, indicating that since the two treatments are not statistically different, they are potentially similar with regard to growth velocities. These data are not sufficient to demonstrate non-inferiority (the registration study endpoint accepted by the FDA for the approval of other treatments for PGHD) and therefore not sufficient to seek approval of LUM-201 at this time. Additionally, given the small number of patients, Lumos cannot exclude the possibility that the results are due to chance alone and may not be reproducible in a larger study. However, Lumos believes this post hoc analysis utilizing t-tests is adequate to generate the hypothesis that Lumos can allocate PGHD patients into PEM-Positive and PEM-Negative populations prospectively in planned clinical trials of LUM-201 in PGHD. Lumos' Phase 2 trial will explore this hypothesis prospectively and seek to determine a dose of LUM-201 that, when administered to PEM-Positive patients, can produce growth that is similar to PEM-Positive patients who are administered rhGH. If an appropriate dose is demonstrated by this Phase 2 trial, any planned Phase 3 trial will be designed to show non-inferiority to rhGH, and will need to satisfy the predefined statistical parameters of non-inferiority as agreed with the FDA at that time. The statistical parameters used to show non-inferiority in the Phase 3 trial will be distinct from the t-test used to analyze the previous data. The statistical analysis required to demonstrate efficacy of LUM-201, like any investigational drug candidate, is a matter of scientific, statistical, and regulatory review by the FDA and any approval of a drug candidate is a matter of comprehensive review of all available data by the FDA. There is no single p-value threshold or statistical methodology such as confidence interval that guarantees approval by the FDA. Lumos believes that its planned Phase 2b Trial using the previously described Predictive Enrichment Markers ("PEMs") to select patients will provide the data needed to select an appropriate LUM-201 dose to use in a Phase 3 non-inferiority study or to show that the hypothesis is incorrect and there is no development path for LUM-201 in PGHD.

In order to better plan for appropriate doses for future clinical trials, Lumos analyzed previous clinical pharmacokinetic ("**PK**") / pharmacodynamic ("**PD**," and together with PK, "**PK/PD**") data in adults and children. Figure 6 is a graph of the PD effect (circulating growth hormone levels) found after increasing doses of LUM-201 are given to normal healthy volunteers. What can be observed is that increasing doses of LUM-201 stimulate the release of increasing amounts of circulating GH up until a 100 mg fixed dose of LUM-201. There is no increase in circulating GH when the dose is further increased to 200 mg. This indicates a plateau in GH release that may be initiated by the naturally occurring feedback mechanism discussed above. The effect of GHRH in this population is also shown (GRF in graph). Lumos sought to relate this PD effect in normal healthy adults to a PD response in growth hormone deficient children by plotting the GH Cmax of each curve in Figure 6 with the mean Cmax of PEM-Positive subjects enrolled in the treatment naïve (Study 020) trial after a single 0.8 mg/kg dose of LUM-201. The mean pediatric PD response (blue circle) falls on the adult PD dose response curve taking into account differences in exposure between adults and children and indicates that higher doses of LUM-201 in children with GHD should be able to produce more GH which has the potential to increase height velocity in children with a functional but underperforming axis.

Figure 6: Mean GH responses following single oral doses of LUM-201 and a single IV dose of GH releasing hormone (GRF) 1 ug/kg in healthy young male volunteers

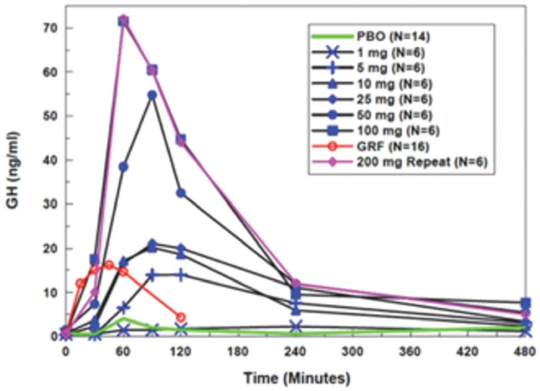
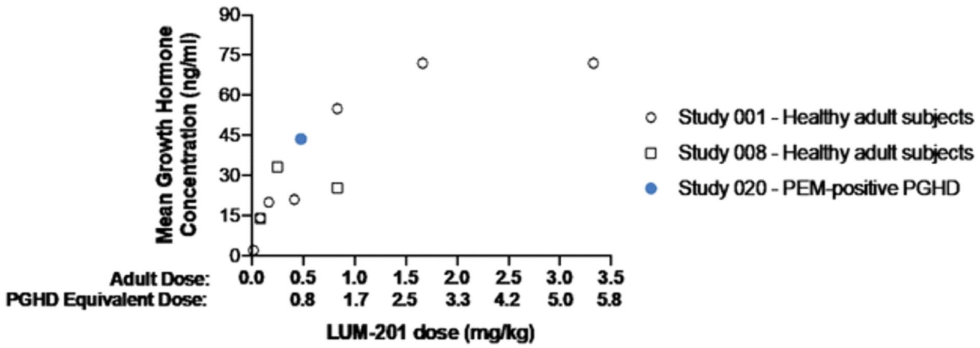


Figure 7: Mean Cmax of GH after ascending doses of LUM-201 in healthy adults and a single 0.8 mg/kg dose of LUM-201 in PGHD subjects



Clinical development plan for PGHD

Lumos is planning to initiate a clinical development program to study the effects of LUM-201 in PGHD by the end of 2020 with a Phase 2b Trial. The primary focus for this Phase 2b Trial is to generate the efficacy and safety data necessary to move LUM-201 into a Phase 3 registration trial. There are also two additional expectations Lumos has set for this trial. The first is to prospectively confirm the utility of Lumos' pre-determined predictive enrichment markers in selecting patients it expects to respond to LUM-201. The second is to determine the optimal dose of LUM-201 to move forward in the Phase 3 trial. The Phase 2b Trial will treat naïve-to-treatment patients and randomize them to one of 4 treatment arms; 3 different doses of LUM-201, 0.8, 1.6, and 3.2 mg/kg, and a comparator arm of standard of care dosing injectable recombinant human GH. Dosing will be administered over 6 months, with annualized growth height velocity as the primary outcome measure.

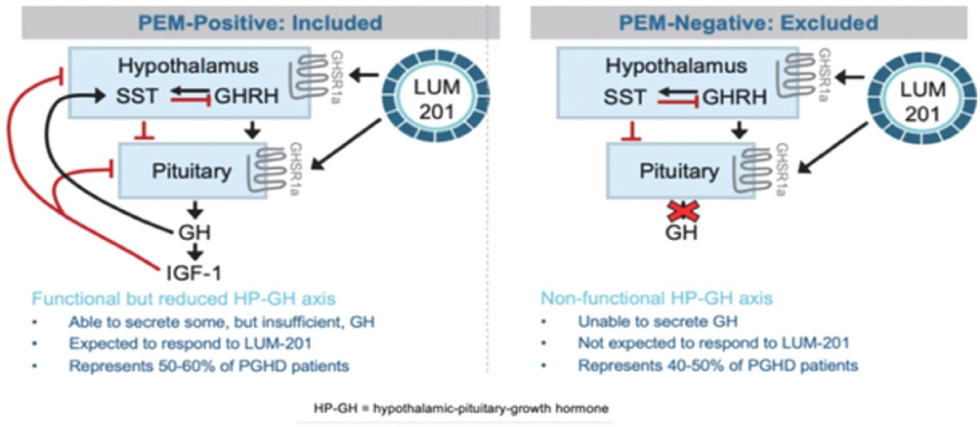
Lumos has received a Study May Proceed letter from the FDA after their review of Lumos' study protocol. As trial initiation is currently delayed by the COVID-19 pandemic, Lumos is evaluating whether there is opportunity within the proposed Phase 2b Trial to address additional FDA feedback that could improve Phase 3 registration readiness. Once subjects finish their participation in the Phase 2b Trial they will be given the opportunity to transition to a long-term safety extension trial.

This trial should enable identification of an expected height velocity range and calculation of the number of patients needed for the proposed follow-on pivotal trial that will assess non-inferiority. The pivotal trial will likely be a 12 month trial with a single dose cohort of oral LUM-201 compared to a control group treated with daily subcutaneous rhGH, with height velocity as the primary endpoint. In addition to these two trials, Lumos also plans to examine the safety and efficacy of LUM-201 in PEM-Positive previously rhGH treated population. During the conduct of these trials Lumos will validate the PEM strategy used to identify the responsive population.

LUM-201 addressable PGHD population

As described above not every PGHD patient has the potential to benefit from LUM-201 treatment. LUM-201 can reactivate a reduced, but intact, hypothalamic pituitary GH axis and restore growth but cannot impact a hypothalamic pituitary GH axis that is unable to produce GH upon stimulation (see Figure 8 below). Lumos believes the PEM strategy outlined above should enable prospective patient selection for upcoming trials to maximize the population that has the best chance for benefit. PGHD encompasses a range of phenotypes from severe to mild. The more severely affected patients would be the least likely to respond to LUM-201 whereas patients with a less severe phenotype would be more likely to benefit from LUM-201 treatment. Lumos believes LUM-201 treatment could address 50% to 60% of the PGHD patient population once approved. This estimate of the addressable population arises from examining existing treatment naïve and previously treated rhGH clinical trial data and available phase 4 rhGH treatment databases.

Figure 8: PEM strategy to prospectively identify LUM-201 addressable patients



Expansion of LUM-201 into Additional Endocrine Indications

There are 11 approved orphan indications for rhGH. PGHD is the first targeted indication to assess the efficacy of LUM-201 and the use of Lumos' PEM strategy to select patients. If LUM-201 demonstrates the ability to increase height velocity in PEM-Positive PGHD subjects, Lumos expects to begin to explore other orphan indications for LUM-201 for which rhGH is approved using Lumos' PEM strategy to select patients. The next two prioritized indications Lumos intends to pursue if LUM-201 demonstrates efficacy in PGHD patients are Turner Syndrome and SGA.

Turner Syndrome results from the complete or partial absence of one of the paired X-chromosomes in females. It is generally considered to be the most common genetic defect among females, occurring in 1:2,500 live births. Based on 1.9 million live female births per year in the United States and a prevalence of 1:2,500, there would be 760 new cases of Turner Syndrome each year and approximately 13,680 cases of Turner Syndrome, ages zero to 18.

Short stature is a cardinal feature of Turner Syndrome with adult heights generally below five feet (1.52 m) and a mean adult height of 56 inches or approximately eight inches below the mean adult female height. Daily injections of rhGH are the standard of care for growth problems in Turner Syndrome. Ovarian dysgenesis is another unifying feature in this syndrome. The expected growth spurt during puberty is generally absent. Co-administration of sex steroids and rhGH during puberty is frequently used to improve end of treatment heights.

A clinical trial exploring efficacy of LUM-201 in PEM-Positive Turner Syndrome patients is planned by Lumos after the Phase 2b Trial has yielded a dose and effect size sufficient to continue clinical development. These parameters will be used to determine doses in a Turner Syndrome trial that will explore LUM-201's effects on height velocity. Lumos believes that the oral delivery of a growth hormone secretagogue would offer advantages in this patient population. Lumos' initial estimates of the addressable population are based on using LUM-201 single dose response values seen in the previous PGHD trials (no Turner Syndrome subject has been treated with LUM-201 yet) and a smaller sample for population estimates than was used for PGHD. With these parameters, Lumos estimates that about 50% of the Turner Syndrome population should respond to LUM-201 and Lumos will further refine these estimates as it generates LUM-201 data in the Turner Syndrome population.

Using the fifth percentiles for birth weight and length as a guide, five percent to 10% of live born children can be classified as small for gestational age. Approximately 10% of these (0.5% to 1.0% of live born children) do not catch up to a normal height by their second birthday. Thus, those individuals born SGA who fail to show catch-up growth (approximately 10%) constitute a relatively high proportion of children and adults with short stature. Based on approximately 4.2 million live births per year based on the 2009 United States Census, these definitions suggest 21,000 to 42,000 pediatric subjects become eligible for treatment each year. A daily injection of rhGH is the standard of care for persistent short stature in children born with SGA.

Lumos expects that a clinical trial exploring the effect of LUM-201 on PEM-Positive patients with SGA would use results from the Phase 2b Trial to assess potentially effective doses for LUM-201 in this patient population. The trial would explore LUM-201's effects on height velocity. Lumos' initial estimates of the addressable population are based on using LUM-201 single dose response values seen in the previous PGHD trials (no SGA subject has been treated with LUM-201 yet) and a smaller sample for population estimates than was used for PGHD. With these parameters Lumos estimates that about 50% of the SGA population should respond to LUM-201 and Lumos will further refine these estimates as it generates LUM-201 data in the SGA population.

Lumos' Commercialization Strategy

Lumos intends to commercialize LUM-201 for PGHD in markets for which marketing exclusivity or patent protection can be obtained, provided it receives regulatory marketing authorization and anticipated product sales are sufficiently robust to justify the expenses required. The initial markets for LUM-201 are expected to include the United States and the European Union, which both offer marketing exclusivity for approved products in orphan diseases. Lumos has received ODD in both territories, which is one necessary component of receiving such exclusivity if approved. Lumos may also target additional markets including China and Japan. Lumos intends to seek ODD in Japan at the appropriate time. Other territories, such as China, do not offer ODD exclusivity periods. In order to protect against generic product market intrusion Lumos will seek patent protection for the use of LUM-201 in PGHD. See "- Intellectual Property" for more details.

Lumos currently has no sales, manufacturing, production or distribution capabilities. Lumos expects to enter into arrangements with third parties to manufacture, produce, market and sell LUM-201 and any other product candidates in one or multiple geographies. Lumos may not be able to enter into such arrangements with others on acceptable terms, if at all.

If one or more of Lumos' product candidates receives regulatory approval, Lumos expects to establish a specialty sales organization with technical expertise and supporting distribution capabilities to co-promote and/or commercialize its product candidates, which will be expensive and time consuming. As a company, Lumos has no prior experience in the sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including Lumos' ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, comply with regulatory requirements applicable to the marketing and sale of drug products and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of Lumos' internal sales, marketing and distribution capabilities with respect to a non-licensed product candidate would adversely impact the commercialization of LUM-201 or other product candidates.

Lumos currently has no international infrastructure including, without limitation, sales, manufacturing and distribution capabilities. Establishing and expanding commercial activities and complying with laws in foreign jurisdictions may be costly and could disrupt Lumos' operations.

Lumos may choose to work with third parties that have direct sales forces and established manufacturing, production and distribution systems, either to augment its own sales force and systems or in lieu of its own sales force and systems. If Lumos is unable to enter into such arrangements on acceptable terms or at all, it may not be able to successfully commercialize its product candidates.

Competition

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

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

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

Intellectual Property

Lumos has been assigned U.S. Patent Nos. 9763919 and 10105352, "Detecting and Treating Growth Hormone Deficiency." The patents are not due to expire in the United States before 2036 and potentially could be issued in multiple other countries for which patent applications have been filed. More specifically, related patent applications have been filed by Ammonett (such patent applications now owned by Lumos) in Australia, Brazil, Canada, China, the European Patent Office, Israel, Japan, the Republic of Korea, New Zealand, Singapore, and Ukraine. U.S. Patent Application Serial No. 16/136967 is also currently pending. The composition of matter patent for LUM-201 has expired and the chemical structure for LUM-201 is in the public domain. However, Lumos has been granted a U.S. method of use patent (and similar applications pending in other regions) directed at growth hormone deficiency disorders.

The claims of U.S. Patent Nos. 9763919 and 10105352 are directed to the use of LUM-201 (previously MK-0677) in a method of treating GH deficiency in children. The patents require patients meet certain PEMs related to a partially functioning hypothalamic-pituitary GH axis.

Lumos also has exclusive rights to a patent application PCT/US19/017964 titled "Compositions for the Treatment of NAFLD and Non-Alcoholic Steatohepatitis." The United States application was converted to a non-provisional application in February of 2019. Lumos may elect to seek collaborations to develop LUM-201 for these indications in the future.

APA, Lumos Merck Agreement and Other Agreements

Ammonett and Lumos Merck Agreements

In July 2018, Lumos acquired any and all rights related to LUM-201 from Ammonett pursuant to the APA by and between Merck and Ammonett. Under the APA, Lumos has the obligation to use commercially reasonable efforts to develop products towards regulatory approval in specified major market countries and to commercialize each product after obtaining regulatory approval. In accordance with the APA, Lumos agreed to pay Ammonett an upfront fee of $3.5 million, development milestone payments totaling up to $17 million for achievement of specified milestones on the first LUM-201 indication that Lumos pursues and up to $14 million for achievements of specified milestones on the second LUM-201 indication that Lumos pursues, sales milestone payments totaling up to $55 million on worldwide product sales, and royalty payments based on worldwide product sales, as discussed below.

In connection with the APA, Lumos was assigned the exclusive, worldwide license and collaboration agreement entered into in November 2014 by and between Ammonett and Merck (the "**Lumos Merck Agreement**"), which grants Lumos (as successor in interest to Ammonett) worldwide, exclusive, sublicensable (subject to Merck's consent in the United States, major European countries and Japan, such consent not to be unreasonably withheld) rights under specified patents and know-how to develop, manufacture and commercialize LUM-201 for any and all indications, excluding Autism Spectrum Disorders as defined in the Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders. As part of the Lumos Merck Agreement, Merck has a co-exclusive research license with Lumos, which permits Merck certain rights, which are sublicensable, to make and use LUM-201 for research purposes, but not commercialization. Pursuant to the Lumos Merck Agreement, Lumos must notify Merck if it intends to enter into a development or commercial arrangement with a third party relating to products licensed under the Lumos Merck Agreement, at which time Merck will have a specified period of time to propose terms for a development or commercial arrangement and upon any exercise of such option, the parties will negotiate the terms to enter into a definitive agreement for such development or commercialization for a specified period of time. Under the Lumos Merck Agreement, Lumos is obligated to use diligence efforts to develop and commercialize licensed products in specified major market countries, including the obligation to launch a licensed product in a country within a specified time period after obtaining regulatory approval in such country.

In consideration for the rights set forth in the Lumos Merck Agreement, Merck initially received an upfront fee from Ammonett. Lumos will be required to pay Merck substantial development milestone payments for achievement of specified milestones relating to each of the first and second indications. Total potential development milestone payments are required of up to $14 million for the first LUM-201 indication that Lumos pursues and up to $8.5 million for the second LUM-201 indication that Lumos pursues. Tiered sales milestone payments totaling up to $80 million are required on worldwide net product sales up to $1 billion, and substantial royalty payments based on product sales are required if product sales are achieved.

If product sales are ever achieved, Lumos is required to make royalty payments under both the APA and the Lumos Merck Agreement collectively of 10% to 12% of total annual product net sales, subject to standard reductions for generic erosion. The royalty obligations under the Lumos Merck Agreement are on a product-by-product and country-by-country basis and will last until the later of expiration of the last licensed patent covering the product in such country and expiration of regulatory exclusivity for such product in such country. The royalty obligations under the APA are on a product-by-product and country-by-country basis for the duration of the royalty obligations under the Lumos Merck Agreement and thereafter until the expiration of the last patent assigned to Lumos under the APA covering such product in such country.

The Lumos Merck Agreement shall continue in force until the expiration of royalty obligations on a country-by-country and product-by-product basis, or unless terminated by Lumos at will by submitting 180 days' advance written notice to Merck or by either party for the other party's uncured material breach or specified bankruptcy events. Upon expiry of the royalty obligations the Lumos Merck Agreement converts to a fully paid-up, perpetual non-exclusive license.

If the Lumos Merck Agreement is terminated, and upon Merck's written request, Lumos is obligated to use reasonable and diligent efforts to assign to Merck any sublicenses previously granted by Lumos.

Agreements in connection with LUM-001

In March 2012, Lumos entered into a license agreement with the University of Cincinnati primarily related to the product candidate LUM-001. Under the license agreement, LUM-001 was developed and advanced to initial clinical trials in 2016. During the conduct of the first trial a non-clinical toxicology signal was observed, leading to the voluntary halt of clinical development. In 2019, the decision was made to discontinue development of LUM-001. Lumos terminated the license agreement in October 2019. No payments were required of Lumos in connection with such termination.

Lumos conducted a natural history (non-interventional) clinical trial (NCT02931682) from 2015 to 2019, evaluating the natural course of CTD progression. In connection with this trial, Lumos entered into various clinical trial agreements ("**CTAs**") with sponsor sites and collaborators. In 2019, Lumos agreed to transfer responsibility for all such activities to Ultragenyx. All such CTAs and other agreements related to the trial have been transferred to Ultragenyx or terminated.

In November 2012, Lumos and certain other parties entered into a settlement agreement related to litigation with The Avicena Group, Inc. and its Chief Executive Officer related to disputes in connection with the patent for LUM-001. The settlement agreement provided that Lumos will not, among other things, develop, commercialize, market, sell, license, transfer or otherwise exploit any substance, therapeutic, diagnostic or other methodology in the dermatological field or the fields of Parkinson's, Huntington's and ALS diseases for a period of 25 years.

Manufacturing

Lumos currently does not own, nor does it plan to own, facilities for clinical or commercial manufacturing of its sole product candidate, LUM-201. Lumos has an existing supply of the LUM-201 active pharmaceutical ingredient ("**API**") obtained in connection with the Lumos Merck Agreement that it believes will be sufficient for its Phase 2b Trial. Lumos is in the process of performing a technology evaluation and optimization with a third-party to manufacture additional API for any further clinical trials. Lumos has an existing arrangement with a contract manufacturer to produce clinical drug product supply for the Phase 2b Trial.

Government Regulations

United States-FDA process

In the United States, the FDA regulates drugs. The Federal Food, Drug, and Cosmetic Act, 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 IND application must be obtained before clinical testing of drugs is initiated, and each clinical trial protocol for drug candidates is reviewed by the FDA prior to initiation in the United States. FDA approval also must be obtained before marketing of drugs in the United States. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, provincial, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and Lumos may not be able to obtain the required regulatory approvals.

Approval process

The FDA must approve any new drug or a drug with certain changes to a previously approved drug before a manufacturer can market it in the United States. If a company does not comply with applicable United States requirements it may be subject to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, warning or untitled letters, clinical holds, drug recalls, drug seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. The steps Lumos must complete before it can market a drug include:

- completion of preclinical laboratory tests, animal studies, and formulation studies performed in accordance with the applicable good laboratory practice ("**GLP**") and other regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials start; the sponsor must update the IND annually;
- approval of the trial by an 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 to establish the safety and efficacy of the drug for each indication to the FDA's satisfaction;
- submission to the FDA of a non-disclosure agreement (an "NDA");
- potential review of the drug application by an FDA advisory committee, where appropriate and if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities to assess compliance with cGMP or other regulations, including licensing requirements and regulations promulgated by state regulatory authorities; and
- FDA review and approval of the NDA.

It generally takes companies many years to satisfy the FDA approval requirements, but this varies substantially based upon the type, complexity, and novelty of the drug or disease. Preclinical tests include laboratory evaluation of a drug's chemistry, formulation, and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the drug. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP. The company submits the results of the preclinical testing to the FDA as part of an IND along with other information, including information about the product drug's chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after submitting the initial IND.

The FDA requires a 30-day waiting period after the submission of each IND before the company can begin clinical testing in humans. The FDA may, within the 30-day time period, raise concerns or questions relating to one or more proposed clinical trials and place the trial on a clinical hold. In such a case, the company and the FDA must resolve any outstanding concerns before the company begins the clinical trial. Accordingly, the submission of an IND may or may not be sufficient for the FDA to permit the sponsor to start a clinical trial. The company must also make a separate submission to an existing IND for each successive clinical trial conducted during drug development.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other requirements, the sponsor must develop methods for ensuring the quality of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its labeled shelf life.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

As product candidates are developed through pre-clinical to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize products, processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause Lumos' product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of Lumos' product candidates and/or jeopardize its or its collaborators' ability to commence product sales and generate revenue.

Clinical trials

Clinical trials involve administering the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. The company must conduct clinical trials:

- in compliance with federal regulations;
- in compliance with good clinical practices ("**GCP**"), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors, and requirements of the IRB; as well as
- under protocols detailing the objectives of the trial, the safety monitoring parameters, and the effectiveness criteria.

The company must submit each protocol involving testing on United States patients and subsequent protocol amendments to the FDA as part of the IND application. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the sponsor is not conducting the clinical trial in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The sponsor must also submit the trial protocol and informed consent information for patients in clinical trials to an IRB for approval. An IRB may halt the clinical trial, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Companies generally divide the clinical investigation of a drug into three or four phases. While companies usually conduct these phases sequentially, they are sometimes overlapped or combined.

- *Phase 1*. The company evaluates the drug in healthy human subjects or patients with the target disease or condition. These trials typically evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the adverse events associated with increasing doses, and if possible, gain early evidence on effectiveness.
- *Phase 2*. The company administers the drug to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse events and safety risks, and preliminarily evaluate efficacy.
- *Phase 3*. The company administers the drug to an expanded patient population, generally at geographically dispersed clinical trial sites, to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug, and to provide an adequate basis for product approval.

- *Phase 4*. In some cases, the FDA may condition approval of an NDA for a drug on the company's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Lumos typically refers to such post-approval trials as Phase 4 clinical trials.

A pivotal trial is a clinical trial that adequately meets regulatory agency requirements to evaluate a drug's efficacy and safety to justify the approval of the drug. Generally, pivotal trials are Phase 3 trials, but the FDA may accept results from Phase 2 trials if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations in which there is an unmet medical need and the results are sufficiently robust.

The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, may oversee some clinical trials. This group provides authorization for whether or not a trial may move forward at designated checkpoints based on access to certain data from the trial. Lumos may also suspend or terminate a clinical trial based on evolving business objectives and the competitive climate.

Submission of an NDA

After completing the required clinical testing, Lumos can prepare and submit an NDA to the FDA, who must approve the NDA before Lumos can start marketing the drug in the United States. An NDA must include all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the drug's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials on a drug, or from a number of alternative sources, including trials initiated by investigators. To support marketing authorization, the data Lumos submits must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug to the FDA's satisfaction.

The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual program user fees. The FDA typically increases these fees annually. ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers.

The FDA has 60 days from its receipt of an NDA to determine whether it will accept the application for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. Once the FDA accepts the filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Under the Prescription Drug User Fee Act, the FDA has a goal of responding to standard review NDAs within ten months after the 60-day filing review period, but this timeframe is often extended. The FDA reviews most applications for standard review drugs within ten to 12 months and most applications for priority review drugs within six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists.

The FDA may also refer applications for novel drugs that present difficult questions of safety or efficacy, to an advisory committee. This is typically a panel that includes clinicians and other experts that will review, evaluate, and recommend whether the FDA should approve the application. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP, and will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the drug unless compliance with cGMP is satisfactory and the NDA contains data that provide evidence that the drug is safe and effective in the indication studied.

The FDA's decision on an NDA

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter indicates that the FDA has completed its review of the application, and the agency has determined that it will not approve the application in its present form. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional clinical data and/or other significant, expensive, and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. The FDA has committed to reviewing resubmissions of the NDA addressing such deficiencies in two or six months, depending on the type of information included. Even if Lumos submits such data the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Also, the government may establish additional requirements, including those resulting from new legislation, or the FDA's policies may change, which could delay or prevent regulatory approval of Lumos' drugs under development.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a 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 Lumos can implement the change. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing new NDAs. As with new NDAs, the FDA often significantly extends the review process with requests for additional information or clarification.

Post-approval requirements

The FDA regulates drugs that are manufactured or distributed pursuant to FDA approvals and has specific requirements pertaining to recordkeeping, periodic reporting, drug sampling and distribution, advertising and promotion and reporting of adverse experiences with the drug. After approval, the FDA must provide review and approval for most changes to the approved drug, such as adding new indications or other labeling claims. There also are continuing, annual user fee requirements for any marketed drugs and the establishments who manufacture its drugs, as well as new application fees for supplemental applications with clinical data.

In some cases, the FDA may condition approval of an NDA for a drug on the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Such post-approval trials are typically referred to as Phase 4 clinical trials.

Drug manufacturers are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. There are strict regulations regarding changes to the manufacturing process, and, depending on the significance of the change, it may require prior FDA approval before Lumos can implement it. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon Lumos and any third-party manufacturers that Lumos may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if a company does not comply with regulatory requirements and maintain standards or if problems occur after the drug reaches the market. If a company or the FDA discovers previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, issues with manufacturing processes, or the company's failure to comply with regulatory requirements, the FDA may revise the approved labeling to add new safety information; impose post-marketing trials or other clinical trials to assess new safety risks; or impose distribution or other restrictions under a REMS program. Other potential consequences may include:

- restrictions on the marketing or manufacturing of the drug, complete withdrawal of the drug from the market or drug recalls;
- fines, warning letters or holds on post-approval clinical trials;
- the FDA refusing to approve pending NDAs or supplements to approved NDAs, or suspending or revoking of drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of drugs that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Lumos could be subject to significant liability if it violated these laws and regulations.

Orphan drug designation

The FDA may grant ODD to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a drug receives FDA approval for the indication for which it has orphan designation, the drug may be entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the drug with orphan exclusivity.

Pediatric information

Under the Pediatric Research Equity Act (the "**PREA**"), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which the FDA has granted an orphan designation.

Healthcare reform

In the United States and foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of legislative and regulatory changes to the healthcare system that could affect its future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reform the way in which healthcare is funded and reduce healthcare costs. In March 2010, the 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;
- new requirements under the federal Physician Payments Sunshine Act for drug manufacturers to report information related to payments and other transfers of value made to physicians and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members; and
- new requirement to annually report certain drug samples that manufacturers and distributors provide to licensed practitioners, or to pharmacies of hospitals or other healthcare entities.

Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Although the Texas U.S. District Court Judge, as well as the presidential administration and the Centers for Medicare & Medicaid Services ("**CMS**") have stated that the ruling will have no immediate effect pending appeal of the decision. On July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case.

Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the PPACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." More recently, in December 2018, CMS published a new final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment.

In addition, other health reform measures have been proposed and adopted in the United States since PPACA was enacted. For example, as a result of the Budget Control Act of 2011, as amended, providers are subject to Medicare payment reductions of two percent per fiscal year through 2027 unless additional Congressional action is taken. Further, the 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.

More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services (the "**HHS**"), has already started the process of soliciting feedback on some of these measures and, at the same, is implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. While some proposed measures will require additional authorization legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In addition, certain members of Congress and the Trump Administration separately have proposed certain measures to limit drug price increases, including providing for the ability of federal government agencies to negotiate drug prices with pharmaceutical companies. Such legislation may be further considered in 2020 and years to come and impact Lumos' revenue in the future.

European Union-EMA process

In the European Union, Lumos' product candidates may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if an MA, from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, guidelines on GCP. Although the European Union Clinical Trials Directive 2001/20/EC has sought to harmonize the European Union clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the European Union Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. To improve the current system, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, which repealed Directive 2001/20/EC, was adopted on April 16, 2014 and published in the European Official Journal on May 27, 2014. The Regulation aims at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency. Although the Regulation entered into force on June 16, 2014, it will not be applicable until six months after the full functionality of the IT portal and database envisaged in the Regulation is confirmed. This is not expected to occur until 2019. Until then the Clinical Trials Directive 2001/20/EC will still apply.

Under the current regime, before a clinical trial can be initiated it must be approved in each of the European Union Member States where the trial is to be conducted by two distinct bodies: the National Competent Authority (the "**NCA**"), and one or more Ethics Committees ("**ECs**"). Under the current regime all suspected unexpected serious adverse reactions, 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 European Medicines Agency (the "**EMA**") issues an opinion, the European Commission issues a single marketing authorization valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are: derived from biotechnology processes, such as genetic engineering; contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions; and officially designated orphan drugs. For drugs that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the drug concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

There are also three other possible routes to authorize medicinal products in the European Union, which are available for products that fall outside the scope of the centralized procedure:

- National procedure. National MAs, issued by the competent authorities of the Member States of the 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 marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Lumos does not foresee that any of its current product candidates will be suitable for a National Marketing Authorization ("MA") as they fall within the mandatory criteria for the Centralized Procedure. Therefore, Lumos' product candidates will be approved through Centralized Procedure. At the current time, it is unclear if or when a separate approval process will be needed in Great Britain, after that country exits from the European Union.

Pursuant to Regulation (EC) No 1901/2006, all applications for marketing authorization for new medicines must include the results of trials as described in a pediatric investigation plan (a "**PIP**"), agreed between regulatory authorities and the applicant, unless the medicine is exempt because of a deferral or waiver (e.g., because the relevant disease or condition occurs only in adults). Before the EMA is able to begin its assessment of a centralized procedure MA application, it will validate that the applicant has complied with the agreed pediatric investigation plan. The applicant and the EMA may, where such a step is adequately justified, agree to modify a pediatric investigation plan to assist validation. Modifications are not always possible; it may take longer to agree than the period of validation permits; and may still require the applicant to withdraw its 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 must be submitted at any stage of development of the drug before filing of an MA application.

If a centralized procedure MA in respect of an orphan drug is granted pursuant to Regulation (EC) No 726/2004, regulatory authorities will not, for a period of usually 10 years, accept another application for an MA, or grant an MA or accept an application to extend an existing MA, for the same therapeutic indication, in respect of a similar drug. This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the drug concerned, that the criteria for ODD are no longer met, in other words, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. The exclusivity period may increase to 12 years if, among other things, the MAA includes the results of trials from an agreed pediatric investigation plan. Notwithstanding the foregoing, an MA may be granted for the same therapeutic indication to a similar drug if:

- the holder of the MA for the original orphan drug has given its consent to the second applicant;
- the holder of the MA for the original orphan drug is unable to supply sufficient quantities of the drug; or
- the second applicant can establish in the application that the second drug, although similar to the orphan drug already authorized, is safer, more effective or otherwise clinically superior.

Regulation (EC) No 847/2000 lays down definitions of the concepts ‘similar drug’ and ‘clinical superiority.’ Other incentives available to orphan drugs in the European Union include financial incentives such as a reduction of fees or fee waivers and protocol assistance. ODD does not shorten the duration of the regulatory review and approval process.

Good manufacturing practices

Like the FDA, the EMA, the competent authorities of the European Union Member States and other regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacturing of drugs prior to approving a drug.

If, after receiving clearance from regulatory agencies, a company makes a material change in manufacturing equipment, location, or process, additional regulatory review and approval may be required. Once Lumos or Lumos’ partners commercialize drugs, Lumos will be required to comply with cGMP, and drug-specific regulations enforced by the European Commission, the EMA and the competent authorities of European Union Member States following drug approval. Also like the FDA, the EMA, the competent authorities of the European Union Member States and other regulatory agencies also conduct regular, periodic visits to reinspect equipment, facilities, and processes following the initial approval of a drug. If, as a result of these inspections, the regulatory agencies determine that Lumos or its partners’ equipment, facilities, or processes do not comply with applicable regulations and conditions of drug approval, they may seek civil, criminal or administrative sanctions and/or remedies against Lumos, including the suspension of its manufacturing operations or the withdrawal of Lumos’ drug from the market.

Post-approval controls

The holder of a European MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (“**PSURs**”).

All new MAAs must include a risk management plan (an “**RMP**”), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under European Union directives, the details are governed by regulations in each European Union Member State and can differ from one country to another.

Data and market exclusivity

Similar to the United States, there is a process to authorize generic versions of innovative drugs in the European Union. Generic competitors can, where data exclusivity has expired, submit abridged applications to authorize generic versions of drugs authorized by EMA through a centralized procedure referencing the innovator's data and demonstrating bioequivalence to the reference drug, among other things. If a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved. This system is usually referred to as "8+2". There is also a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Other international markets-drug approval process

In some international markets (such as China or Japan), although data generated in United States or European Union trials may be submitted in support of a marketing authorization application, regulators may require additional clinical trials conducted in the host territory, or studying people of the ethnicity of the host territory, prior to the filing or approval of marketing applications within the country.

Pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drugs for which Lumos may obtain regulatory approval. In the United States and markets in other countries, sales of any drugs for which Lumos receives regulatory approval for commercial sale will depend on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug may be separate from the process for setting the reimbursement rate that the payor will pay for the drug. Third-party payors may limit coverage to specific drugs on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Moreover, a payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Additionally, coverage and reimbursement for drugs can differ significantly from payor to payor. One third-party payor's decision to cover a particular drug does not ensure that other payors will also provide coverage for the drug, or will provide coverage at an adequate reimbursement rate. Adequate third-party reimbursement may not be available to enable Lumos to maintain price levels sufficient to realize an appropriate return on its investment in drug development.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of drugs and services, in addition to their safety and efficacy. To obtain coverage and reimbursement for any drug that might be approved for sale, Lumos may need to conduct expensive pharmacoeconomic trials to demonstrate the medical necessity and cost-effectiveness of its drug. These trials will be in addition to the trials required to obtain regulatory approvals. If third-party payors do not consider a drug to be cost-effective compared to other available therapies, they may not cover the drug after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its drugs at a profit.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs for branded prescription drugs. By way of example, PPACA contains provisions that may reduce the profitability of drugs, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for Lumos' drugs.

In the European Community, governments influence the price of drugs through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those drugs to consumers. Some jurisdictions operate positive and negative list systems under which drugs may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new drugs. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any drugs for which Lumos receives 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 Lumos expects will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if Lumos attains favorable coverage and reimbursement status for one or more drugs for which Lumos receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other healthcare laws impacting sales, marketing, and other company activities

Numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the HHS, the U.S. Department of Justice, and similar foreign, state, and local government authorities, regulate and enforce laws and regulations applicable to sales, promotion and other activities of pharmaceutical manufacturers. These laws and regulations may impact, among other things, Lumos' clinical research programs, proposed sales and marketing and education activities, and financial and business relationships with future prescribers of Lumos' product candidates, once approved. These laws and regulations include U.S. federal, U.S. state and foreign anti-kickback, false claims, and data privacy and security laws, which are described below, among other legal requirements that may affect Lumos' current and future operations.

The FDA regulates all advertising and promotion activities for drugs under its jurisdiction both prior to and after approval. Only those claims relating to safety and efficacy that the FDA has approved may be used in labeling once the drug is approved. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those Lumos tested and the FDA approved. Such off-label uses are common across medical specialties, and often reflect a physician's belief that the off-label use is the best treatment for the patients. The FDA does not regulate the behavior of physicians in their choice of treatments, but FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. If Lumos does not comply with applicable FDA requirements Lumos may face adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA. Promotion of off-label uses of drugs can also implicate the false claims laws described below.

Anti-kickback laws including, without limitation, the federal Anti-Kickback Statute that applies to items and services reimbursable under governmental healthcare programs such as Medicare and Medicaid, make it illegal for a person or entity to, among other things, knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, to induce, or in return for, purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service reimbursable, in whole or in part, under a federal healthcare program. Due to the breadth of the statutory provisions, limited statutory exceptions and regulatory safe harbors, and the scarcity of guidance in the form of regulations, agency advisory opinions, sub-regulatory guidance and judicial decisions addressing industry practices, it is possible that Lumos' practices might be challenged under anti-kickback or similar laws. Moreover, recent healthcare reform legislation has strengthened these laws. For example, PPACA among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statute to clarify that a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a crime. In addition, PPACA clarifies that the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

False claims laws, including, without limitation, the federal civil False Claims Act, prohibit, among other things, anyone from knowingly and willingly presenting, or causing to be presented for payment, to the federal government (including Medicare and Medicaid) claims for reimbursement for, among other things, drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Lumos' activities relating to the sales and marketing of its drugs may be subject to scrutiny under these laws, as well as civil monetary penalties laws and the criminal healthcare fraud provisions enacted as part of the federal Health Insurance Portability and Accountability Act of 1996 ("**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) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members.

In addition, Lumos may be subject to state law equivalents of each of the above federal laws, such as anti-kickback, self-referral, and false claims laws which may apply to Lumos' business practices, including but not limited to, research, distribution, sales and marketing arrangements and submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical manufacturers to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers; state laws that require pharmaceutical manufacturers to file reports with states regarding drug pricing and/or marketing information, such as the tracking and reporting of gifts, compensation and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Violations of these laws may result in criminal, civil and administrative sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement, contractual damages, reputational harm and the imposition of corporate integrity agreements or other similar agreements with governmental entities, which may impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as individual imprisonment, also can be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called "responsible corporate officer" doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing. Given the significant penalties and fines that can be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions and additional corporate integrity obligations. If the government were to allege or convict Lumos or Lumos' executive officers of violating these laws, Lumos' business could be harmed.

Similar rigid restrictions are imposed on the promotion and marketing of drugs in the European Union and other countries. Even in those countries where Lumos may not be directly responsible for the promotion and marketing of Lumos' drugs, if Lumos' potential international distribution partners engage in inappropriate activity it can have adverse implications for Lumos.

Legal Proceedings

Lumos is not currently a party to any material legal proceedings. From time to time, Lumos may be involved in various claims and legal proceedings relating to its operations. Regardless of outcome, litigation can have an adverse impact on Lumos because of defense and settlement costs, diversion of management resources and other factors.

Facilities

Lumos' corporate headquarters are in Austin, Texas, where it occupies approximately 5,000 square feet of office space under a lease expiring on November 1, 2021. Lumos also has facilities in the Iowa State University Research Park in Ames, Iowa, which total approximately 26,616 square feet, and comprise executive office space and space dedicated to manufacturing, testing and product storage, leased with the Iowa State University Research Park Corporation. The lease expires March 31, 2021, and Lumos does not intend to exercise its option to extend the lease. Lumos leases an additional 3,255 square feet of office space in Wayne, Pennsylvania under a lease that expires in February 2021. On February 28, 2020, Lumos signed a sublease agreement for the Wayne, Pennsylvania space. Lumos believes its existing facilities meet its current needs and Lumos has convenient access to additional space on reasonable terms for its future needs.

Employees

As of March 31, 2020, Lumos had 25 full-time employees, and 1 part-time employee, as well as 5 regularly engaged consultants. None of Lumos' employees are represented by any collective bargaining agreements. Lumos believes that it maintains good relations with its employees.

SELECTED HISTORICAL CONSOLIDATED FINANCIAL DATA OF LUMOS

The selected consolidated statements of operations data for the years ended December 31, 2018 and 2019 and the selected consolidated balance sheet data as of December 31, 2018 and 2019 are derived from Lumos' audited consolidated financial statements included elsewhere in this Current Report on Form 8-K/A. Lumos' historical results are not necessarily indicative of the results that may be expected in any future period.

The selected historical consolidated financial data below should be read in conjunction with the section titled "Lumos Management's Discussion and Analysis of Financial Condition and Results of Operations," and Lumos' consolidated financial statements and related notes included elsewhere in this Current Report on Form 8-K/A.

Consolidated Statements of Operations Data:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Operating expenses:		
Research and development	$ 5,669	$ 5,253
In-process research and development	—	3,500
General and administrative, including stock-based compensation of $179 and $199, respectively	4,147	2,533
Total operating expenses	9,816	11,286
Loss from operations	(9,816)	(11,286)
Other income, net:		
Interest and other income, net	111	124
Net loss	$ (9,705)	$ (11,162)

Consolidated Balance Sheet Data:

	As of December 31,	
	2019	2018
	(in thousands, except share and per share amounts)	
Assets		
Current assets		
Cash and cash equivalents	$ 4,952	$ 14,022
Prepaid and and other current assets	117	202
Total current assets	5,069	14,224
Non-Current Assets		
Right-of-use asset	373	—
Property and equipment, net of accumulated depreciation and amortization of $154 and $124, respectively	84	112
Total non-current assets	457	112
Total assets	$ 5,526	$ 14,336
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 365	$ 189
Accrued compensation	345	234
Other accrued liabilities	364	337
Current portion of lease liability	189	—
Total current liabilities	1,263	760
Long term liabilities:		
Operating lease liability	191	—
Total long-term liabilities	191	—
Total liabilities	1,454	760
Commitments and contingencies		
Redeemable convertible preferred stock:		
Series B redeemable convertible preferred stock, par value $0.0001; 9,966,288 stock authorized, issued and outstanding as of December 31, 2019 and 2018; stated at accreted redemption value	41,631	39,592
Series A redeemable convertible preferred stock, par value $0.0001; 11,204,513 stock authorized, issued and outstanding as of December 31, 2019 and 2018; stated at accreted redemption value	21,904	20,903
Stockholders' deficit:		
Common stock, $0.0001 par value; 36,000,000 shares authorized as of December 31, 2019 and 2018; and 9,003,433 and 10,283,437 shares issued and outstanding as of December 31, 2019 and 2018, respectively	1	1
Treasury stock, at cost, 1,350,000 shares held as of December 31, 2019, none held at December 31, 2018	—	—
Additional paid-in capital	213	12
Accumulated deficit	(59,677)	(46,932)
Total stockholders' equity	(59,463)	(46,919)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 5,526	$ 14,336

See accompanying notes to consolidated financial statements.

LUMOS MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of Lumos' financial condition and results of operations together with the section entitled "Selected Historical Consolidated Financial Data of Lumos" and Lumos' consolidated financial statements and related notes included elsewhere in this Current Report on Form 8-K/A. This discussion and other parts of this Current Report on Form 8-K/A contain forward-looking statements that involve risks and uncertainties, such as its plans, objectives, expectations, intentions and beliefs. Lumos' actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below as well as the section entitled "Risk Factors" identified (i) in NewLink's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and (ii) in NewLink's revised definitive proxy statement filed with the SEC on February 13, 2020, as well as the risk factors included under Item 8.01 of our Current Report on Form 8-K filed with the SEC on May 14, 2020.

Overview

On March 18, 2020, NewLink Genetics Corporation merged Cyclone Merger Sub, Inc., a wholly-owned subsidiary, with what was then known as Lumos Pharma, Inc., and has since been renamed "Lumos Pharma Sub, Inc." and changed the name "NewLink Genetics Corporation" to "Lumos Pharma, Inc." Unless otherwise indicated, references to "Lumos" or the "Company" prior to the Merger refer to Private Lumos, and such references following the Merger, to Lumos Pharma, Inc., formerly known as NewLink Genetics Corporation. References to "NewLink" refer to NewLink Genetics Corporation prior to the Merger.

Lumos is a clinical-stage biopharmaceutical company focused on the identification, acquisition and in-license, development, and commercialization of novel products for the treatment of rare diseases. Lumos' mission is to develop new therapies for people with rare diseases, prioritizing its focus where the medical need is high, and the pathophysiology is clear. Lumos is committed to this mission and a strategy that is grounded upon time and cost-efficient drug development for Lumos to develop and deliver safe and effective therapies to patients. Driven by a sense of commitment to rare disease patients, their families and the rare disease community, the goal of Lumos is to be a leading rare disease drug company.

The current Lumos pipeline is focused on the development of an orally administered small molecule, the GH secretagogue LUM-201, for rare endocrine disorders. A secretagogue is a substance that stimulates the secretion or release of another substance. LUM-201 stimulates the release of GH and is referred to as a GH secretagogue. The current targeted indications for LUM-201 are PGHD, Turner Syndrome and SGA, in each case in a certain subset of affected patients. Lumos plans to initiate a clinical development program to study the effects of LUM-201 in PGHD by the end of 2020 with a Phase 2b Trial. Depending on the outcome of data developed in the Phase 2b Trial and the timing of such data, Lumos plans to conduct Phase 2 clinical trials to study the effects of LUM-201 for Turner Syndrome and SGA in a certain subset of affected patients.

If approved, LUM-201 has the potential to become the first approved oral GH secretagogue to treat rare endocrine disorders associated with GH deficiencies, starting with PGHD, providing an alternative to the current standard regimen of daily injections. Lumos acquired LUM-201 from Ammonett in July 2018. LUM-201 received the ODD in the United States and the European Union for GHD in 2017. The United States patent "Detecting and Treating Growth Hormone Deficiency" has been issued with an expiration in 2036. Other patent applications are pending in multiple jurisdictions.

Since its inception, Lumos' operations have focused on organizing and staffing, business planning, raising capital, acquiring its technology and assets, and conducting preclinical and clinical development of its product candidates. Lumos has devoted substantial effort and resources to acquiring its current product candidate, LUM-201, as well as its previous product candidate, LUM-001, which it ceased developing in 2019. Lumos acquired LUM-201 through its acquisition of substantially all of the assets related to LUM-201 from Ammonett which had licensed LUM-201 in October 2013 from Merck. Lumos does not have any product candidates approved for sale and has not generated any revenue from product sales. Lumos has funded its operations primarily through the sale and issuance of preferred stock, as well as through in-kind support pursuant to a collaborative research and development agreement with the NIH from 2012 to April 2019.

Since inception, Lumos has incurred significant operating losses and negative operating cash flows and there is no assurance that it will ever achieve or sustain profitability. Lumos' net loss was $9.7 million for the year ended December 31, 2019. As of December 31, 2019, Lumos had an accumulated deficit of $59.7 million. Lumos expects to continue to incur significant expenses and increasing operating losses for the foreseeable future. Lumos anticipates that its expenses will increase significantly in connection with its ongoing activities as Lumos:

- continues the ongoing and planned clinical development of LUM-201;
- hires additional administrative, clinical, regulatory and scientific personnel;
- initiates preclinical studies and clinical trials for any additional indications for its current product candidates and any future product candidates that Lumos may pursue;
- builds a portfolio of product candidates through the acquisition or in-license of drugs or product candidates and technologies;
- develops, maintains, expands, and protects its intellectual property portfolio;
- manufactures, or has manufactured, clinical and commercial supplies of its product candidates;
- seeks marketing approvals for its current and future product candidates that successfully complete clinical trials;
- establishes a sales, marketing and distribution infrastructure to commercialize any product candidate for which Lumos may obtain marketing approval; and
- incurs additional costs associated with operating as a public company.

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, which was developed under the NewLink Merck Agreement. On January 3, 2020, Merck notified NewLink that they had been issued a PRV. Under the terms of the NewLink Merck Agreement, on February 4, 2020, Merck assigned all of its rights and interests in connection with the PRV to NewLink.

As a result of such arrangements, Lumos is entitled to 60% of the value of the PRV obtained through sale, transfer or other disposition of the PRV. Lumos also has the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is successfully commercialized by Merck. However, Lumos believes 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 Lumos does not expect to receive material royalty payments from Merck in the foreseeable future.

Components of Results of Operations

Research and development expense

Research and development expenses for 2019 consist primarily of costs incurred in connection with the development of Lumos' current product candidate, LUM-201. Lumos expenses research and development costs as incurred. These expenses include:

- costs of funding research performed by third parties, including pursuant to agreements with CROs, as well as investigative sites and consultants that conduct Lumos' preclinical studies and clinical trials;
- expenses incurred under agreements with contract manufacturing organizations, including manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- payments made under Lumos' third-party licensing agreements, other than amounts classified as acquired in-process research and development expenses;
- personnel costs for Lumos employees involved in the research and development activities;
- consultant fees and expenses associated with outsourced professional scientific development services; and
- expenses for regulatory activities, including filing fees paid to regulatory agencies.

Milestone payment obligations incurred prior to regulatory approval of a product candidate, which are accrued when the event requiring payment of the milestone occurs will be included in research and development expense.

Lumos expects its research and development expense will increase for the foreseeable future as it seeks to advance development of LUM-201. The successful development of LUM-201 is highly uncertain. At this time, Lumos cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of LUM-201. Lumos is also unable to predict when, if ever, material net cash inflows may commence from sales of LUM-201 or any future product candidates Lumos may develop due to numerous factors, including, among others:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the duration of patient follow-up and number of patient visits;
- the results of Lumos' clinical trials;
- the securing of commercial manufacturing capabilities.
- the receipt of marketing approvals; and
- the commercialization of product candidates.

Lumos may never succeed in obtaining regulatory approval for LUM-201 or any future product candidates. Lumos costs will increase as product candidates advance to later stages of clinical development, since later stage products generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

Acquired in-process research and development expense

Acquired in-process research and development expense consists of the initial up-front payments incurred in connection with the acquisition or licensing of product candidates that do not meet the definition of a business under ASC 805, *Business Combinations*. Lumos' acquired in-process research and development expense reflects the cash consideration paid up front in Lumos' acquisition of Ammonett assets related to LUM-201 in July 2018.

General and administrative expense

General and administrative expense consists primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for employees in executive, finance, accounting, business development, legal and human resource functions. General and administrative expense also includes corporate facility costs, including rent, utilities, depreciation, and maintenance, not otherwise included in research and development expense, as well as legal fees related to intellectual property and corporate matters and fees for accounting, recruiting and consulting services.

Lumos anticipates that its general and administrative expense will increase as a result of increased headcount, expanded infrastructure and higher accounting, legal, consulting, and investor relations fees, as well as increased director and officer insurance premiums, associated with being a public company. Lumos also anticipates that its general and administrative expense will increase as it supports clinical trials for LUM-201. In addition, if and when Lumos believes that regulatory approval of LUM-201 appears likely, Lumos anticipates an increase in headcount and expense as a result of its preparation for commercial operations.

Results of operations

The following table sets forth Lumos selected statements of operations data for the periods indicated (in thousands):

	Years ended December 31,		
	2019	**2018**	**2017**
Operating expenses:			
Research and development	$ 5,669	$ 5,253	$ 6,321
Acquired in-process research and development	--	3,500	--
General and administrative	4,147	2,533	2,676
Loss from operations	(9,816)	(11,286)	(8,997)
Other income (net):			
Interest and other income, net	111	124	51
Net loss	$ (9,705)	$ (11,162)	$ (8,946)

Comparison of the years ended December 31, 2019 and 2018

Research and development expense

Research and development expense increased by $0.4 million to $5.7 million for the year ended December 31, 2019 from $5.3 million for the year ended December 31, 2018. The following table summarizes Lumos' research and development expenses for the years ended December 31, 2019 and 2018:

	Years ended December 31	
	2019	2018
	(in thousands)	
Preclinical and clinical development expense	$ 4,018	$ 3,616
Compensation expense	1,513	1,509
Other expenses	138	128
Total research and development expense	$ 5,669	$ 5,253

Total research and development expense increased by $0.4 million or 8% for the year ended December 31, 2019 compared with the year ended December 31, 2018, primarily related to ongoing scaling back of the LUM-001 program offset by the commencement of the LUM-201 program towards the end of 2019.

General and administrative expense

General and administrative expense increased by $1.6 million, from $4.1 million for the year ended December 31, 2019 from $2.5 million for the year ended December 31, 2018. The increase was primarily due to higher legal fees relating to the Merger transaction. The following table summarizes Lumos' general and administrative expenses for the years ended December 31, 2019 and 2018:

	Years ended December 31	
	2019	2018
	(in thousands)	
Compensation expense, other than stock-based compensation	$ 879	$ 812
Professional and legal expense	2,235	724
Stock-based compensation expense	179	199
Other expenses	854	798
Total general and administrative expense	$ 4,147	$ 2,533

Liquidity and Capital Resources

The following table shows a summary of Lumos' cash flows for the periods indicated:

	Years ended December 31,	
	2019	2018
	(in thousands)	
Net cash (used in) operating activities	$ (9,090)	$ (7,190)
Net cash (used in) investing activities	(2)	(3,501)
Net cash provided by financing activities	22	34
Net (decrease) in cash	$ (9,070)	$ (10,657)

Sources of funds

Lumos has funded its operations primarily through the sale and issuance of preferred stock as well as through in-kind support pursuant to a collaborative research and development agreement with the NIH. As of December 31, 2019, Lumos had $5.0 million in cash and cash equivalents and an accumulated deficit of $59.7 million.

Uses of funds

Operating activities

During the year ended December 31, 2019, Lumos used $9.0 million of cash in operating activities. Cash used in operating activities reflected Lumos' net loss of $9.7 million, offset by a net decrease in operating assets and liabilities of $0.4 million and non-cash charges of $0.3 million, primarily related to stock-based compensation. The net change in Lumos' operating assets and liabilities is primarily attributable to the increase in accrued liabilities and accounts payable due to the timing of payments to its vendors.

During the year ended December 31, 2018, Lumos used $7.2 million of cash in operating activities. Cash used in operating activities reflected Lumos' net loss of $11.1 million, offset by a net decrease in operating assets and liabilities of $0.2 million and non-cash charges of $3.7 million, primarily related to the expensing of the in-process research and development acquired and stock-based compensation. The net change in Lumos' operating assets and liabilities is primarily attributable to the increase in accrued liabilities and accounts payable due to the timing of payments to its vendors. Cash used for investing changed primarily due to the $3.5 million of cash paid to acquire in-process research and development.

Funding requirements

Lumos expects its expenses to increase in connection with its ongoing activities, particularly as Lumos continues the research and development of, continues or initiates clinical trials of, and seeks marketing approval for, its product candidate, LUM-201. In addition, if Lumos obtains marketing approval for LUM-201, Lumos expects to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Furthermore, Lumos expects to incur additional costs associated with operating as a public company. Accordingly, Lumos will need to obtain substantial additional funding in connection with its continuing operations. If Lumos is unable to raise capital when needed or on attractive terms, Lumos would be forced to delay, reduce or eliminate its research and development programs or future commercialization efforts.

After completion of the Merger, the combined company will have cash reserves which will be sufficient to meet liquidity and capital requirements for Lumos' current operating plans.

Lumos' future capital requirements will depend on many factors, including:

- the scope, progress, results, and costs of preclinical studies and clinical trials;
- the scope, prioritization, and number of Lumos' research and development programs;
- the costs, timing, and outcome of regulatory review of LUM-201 or any future product candidate;
- Lumos' ability to establish and maintain collaborations on favorable terms, if at all;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing Lumos' intellectual property rights, and defending intellectual property-related claims;
- the extent to which Lumos acquires or in-licenses other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if Lumos obtains regulatory approvals to market its product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and Lumos may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, LUM-201, if approved, may not achieve commercial success. Lumos' commercial revenues, if any, will be derived from sales of LUM-201 that Lumos does not expect to be commercially available for many years, if at all. Accordingly, Lumos will need to continue to rely on additional financing to achieve its business objectives. Adequate additional financing may not be available to Lumos on acceptable terms, or at all.

Until such time, if ever, as Lumos can generate substantial product revenues, Lumos expects to finance its cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that Lumos raises additional capital through the sale of equity or convertible debt securities, the ownership interests of its stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting Lumos' ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If Lumos raises funds through additional collaborations, strategic alliances or licensing arrangements with third parties, Lumos may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to Lumos. If Lumos is unable to raise additional funds through equity or debt financings when needed, Lumos may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market product candidates that Lumos would otherwise prefer to develop and market itself.

Contractual Obligations and Commitments

The following table summarizes Lumos' commitments to settle contractual obligations at December 31, 2019:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
			(in thousands)		
Operating leases[(1)]	$ 204	$ 195	$ --	$ --	$ 399
Total	$ 204	$ 195	$ --	$ --	$ 399

(1) Reflects obligations pursuant to Lumos' office lease in Austin, Texas.

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. The table does not include obligations under agreements that Lumos can cancel without a significant penalty.

Off-Balance Sheet Arrangements

Lumos does not have any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. Lumos does not engage in off-balance sheet financing arrangements. In addition, Lumos does not engage in trading activities involving non-exchange traded contracts. Lumos therefore believes that it is not materially exposed to any financing, liquidity, market or credit risk that could arise if it had engaged in these relationships.

Critical Accounting Policies

Lumos' financial statements are prepared in accordance with GAAP. The preparation of Lumos' financial statements requires Lumos to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reported period. Lumos bases its estimates on historical experience, known trends and events and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Lumos evaluates its estimates and assumptions on an ongoing basis. Lumos' actual results may differ from these estimates under different assumptions and conditions.

While Lumos' significant accounting policies are described in more detail in the notes to its financial statements appearing elsewhere in this Current Report on Form 8-K/A, Lumos believes that the following accounting policies are those most critical to the preparation of its financial statements.

Asset acquisitions

Accounting for transactions as asset acquisitions is significantly different than business combinations. For example, acquired in-process research and development is expensed for asset acquisitions and capitalized for business combinations. Goodwill is only recognized in business combination transactions. The fair value of contingent consideration is recognized in business combination transactions and may be recognized in asset acquisitions if payment is probable and the amount can be estimated. As a result, it is important to determine whether a business or an asset or a group of assets is acquired. A business is defined in ASC 805, *Business Combinations*, as an integrated set of inputs and processes that can generate outputs that have the ability to provide a return to its investors or owners. Typical inputs include long-lived assets (including intangible assets or rights to use long-lived assets), intellectual property and the ability to obtain access to required resources. Typical processes include strategic, operational and resource management processes that are typically documented or evident through an organized workforce.

In January 2017, the Financial Accounting Standards Board ("**FASB**") issued ASU 2017-01, *Clarifying the Definition of a Business* ("**ASU 2017-01**"). A key provision within ASU 2017-01 is the single or similar asset threshold. When substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the acquired set is not a business. Lumos adopted this standard effective January 1, 2018.

Lumos considered all of the above factors when determining whether a business was acquired. In evaluating Lumos' acquisition of substantially all the assets of Ammonett, Lumos concluded virtually all the value was concentrated in the acquired LUM-201 program. As such, Lumos accounted for the transaction as an asset acquisition. The fair value, represented by the up-front cash payment, allocated to the acquired LUM-201 development program was expensed and not capitalized.

Leases

In February 2016, the FASB issued ASU No. 2016-02 (Topic 842), Leases, which requires lessees to recognize right-of-use assets and liabilities on the balance sheet and disclose key information about leasing arrangements. Lumos adopted the standard on January 1, 2019 using the modified retrospective method applying the new standard to all leases existing on the date of initial application. Lumos has elected that the date of the initial application, January 1, 2019, will be the effective date. Consequently, financial information is not updated, and disclosures required under the new standard are not provided for dates and periods prior to January 1, 2019.

Lumos elected the "package of practical expedients", which permits Lumos not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. Lumos did not elect to apply the use-of-hindsight or the practical expedient pertaining to land easements; as the latter is not applicable to Lumos.

Upon adoption of the standard, Lumos recorded a lease liability and right-of-use asset of $555,000 of associated with their lease. There was no material impact to the statement of operations.

Lumos records the lease liability based on the present value of lease payments over the lease term using an incremental borrowing rate to discount its lease liability, as the rate implicit in the lease is not readily determinable. The right-of-use asset is recognized on a straight-line basis over the remaining lease term. To compute the present value of the lease liability, Lumos used a discount rate of 5%. The remaining lease term as of December 31, 2019 is 1.92 years.

Lumos does not separate lease components from non-lease components. Lumos' lease agreement does not contain any residual value guarantees or restrictive covenants.

Research and development expenses

Research and development expenses consist primarily of costs incurred in connection with the development of Lumos' product candidates. Lumos expenses research and development costs as incurred.

Acquired in-process research and development

Acquired in-process research and development expense consists of the initial up-front payments incurred in connection with the acquisition or licensing of product candidates that do not meet the definition of a business under ASC 805, *Business Combinations*.

Stock-based compensation

Lumos measures expense for all stock options based on the estimated fair value of the award on the grant date. Lumos uses the Black-Scholes option pricing model to value its stock option awards. Lumos recognizes compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Lumos has not issued awards where vesting is subject to a market or performance condition; however, if Lumos were to grant such awards in the future, recognition would be based on the derived service period. Expense for awards with performance conditions would be estimated and adjusted on a quarterly basis based upon Lumos' assessment of the probability that the performance condition will be met.

Estimating the fair value of options requires the input of subjective assumptions, including the estimated fair market value of Lumos' common stock, the expected life of the option, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in Lumos' Black-Scholes option-pricing model represent management's best estimates and involve several variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, Lumos' stock-based compensation expense could be materially different in the future.

There assumptions are estimated as follows:

- *Expected Term.* The expected term represents the period that Lumos' stock options are expected to be outstanding. Lumos calculated the expected term using the simplified method based on the average of each option's vesting term and the contractual period during which the option can be exercised, which is typically 10 years following the date of grant.
- *Expected Volatility.* The expected volatility was based on the historical stock volatility of several of Lumos' comparable publicly traded companies over a period of time equal to the expected term of the options, as it does not have any trading history to use the volatility of Lumos' own common stock.
- *Risk-Free Interest Rate.* The-risk-free interest rate was based on the yields of U.S. Treasury securities with maturities appropriate for the term of the award.
- *Expected Dividend Yield.* Lumos has not paid dividends on its common stock nor does it expect to pay dividends in the foreseeable future.
- *Fair Market Value of Common Stock.* As Lumos' common stock has not historically been publicly traded, Lumos has periodically estimated the fair market value of common stock. See "-Fair market value of common stock."

The following table reflects the weighted average assumptions used to estimate the fair value of options granted in the years ended December 31, 2019 and December 31, 2018.

	Years ended December 31	
	2019	**2018**
Expected term (in years)	6.02	5.92
Expected volatility	90%	90%
Risk-free interest rate	1.8%	2.8%
Expected dividend yield	0%	0%
Fair market value of common stock	$ .024	$ .024

Fair market value of common stock

Historically, for all periods prior to the closing of the Merger, the fair market values of the shares of common stock underlying Private Lumos' stock options were estimated on each grant date by the board of directors of Private Lumos. In order to determine the fair market value of Private Lumos' common stock, the board of directors of Private Lumos considered, among other things, contemporaneous valuations of its common and preferred stock prepared by unrelated third-party valuation firms in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Given the absence of a public trading market of Private Lumos' capital stock, the board of directors of Private Lumos exercised reasonable judgment and considered several objective and subjective factors to determine the best estimate of the fair market value of Private Lumos' common and preferred stock, including:

- contemporaneous third-party valuations of Private Lumos' common stock;
- the prices, rights, preferences, and privileges of Private Lumos' preferred stock relative to the common stock;
- Private Lumos' business, financial condition, and results of operations, including related industry trends affecting Private Lumos' operations;
- the likelihood of achieving a liquidity event, such as an IPO or sale of the company, given prevailing market conditions;
- the lack of marketability of Private Lumos' common stock;
- the market performance of comparable publicly traded companies; and
- United States and global economic and capital market conditions and outlook.

There are significant judgments and estimates inherent in the determination of these valuations. These judgments and estimates include assumptions regarding Private Lumos' future performance, including the successful completion of its clinical trials and the time to liquidity, as well as the determination of the appropriate valuation methods at each valuation date. If Private Lumos had made different assumptions, its valuation could have been different. The foregoing valuation methodologies are not the only methodologies available, and they are not used to value the Lumos' common stock.

Recent Accounting Pronouncements

See Notes 2 and 3 to Lumos' financial statements beginning on page 6 of Exhibit 99.2 to this Current Report on Form 8-K/A for a description of recent accounting pronouncements applicable to its financial statements.

FINANCIAL STATEMENTS

Reference is made to the financial statements and pro forma financial information relating to Lumos contained in Item 9.01 of this Current Report on Form 8-K/A, which is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

The audited financial statements of Private Lumos as of and for the years ended December 31, 2019 and 2018 are filed herewith as Exhibit 99.2 and are incorporated herein by reference. The consent of KPMG LLP, Lumos' independent registered public accounting firm, is attached as Exhibit 23.1 to this Current Report on Form 8-K/A.

(b) Pro Forma Financial Information.

Our unaudited pro forma condensed combined balance sheet as of December 31, 2019 and unaudited combined condensed statement of operations for the year ended December 31, 2019 are filed herewith as Exhibit 99.3 and are incorporated herein by reference.

(d) Exhibits.

Exhibit No.	Description
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., as amended
3.1	Certificate of Amendment to Certificate of Incorporation to Effect the Reverse Stock Split
3.2	Certificate of Amendment to Certificate of Incorporation to Effect the Name Change
4.1	Form of Common Stock Certificate
10.1#	Lumos Pharma, Inc. 2012 Equity Incentive Plan
10.2#	2012 Equity Incentive Plan Form of Incentive Stock Option Grant Notice
10.3#	Lumos Pharma, Inc. 2016 Stock Plan
10.4#	2016 Form of Stock Option Grant Notice
10.5#	Form of Indemnity Agreement by and between the Registrant and its directors and officers
10.6*+	License Agreement by and between Merck Sharp & Dohme Corp. and Ammonett Pharma LLC, effective as of October 22, 2013.
10.7*+	Asset Purchase Agreement by and among Lumos Pharma, Inc., Ammonett Pharma LLC, and each of certain individuals listed therein, dated as of July 26, 2018.
23.1*	Consent of KPMG LLP, the Company's independent registered public accounting firm.
99.1	Press release issued by the Company on March 18, 2020
99.2*	Audited financial statements of Private Lumos as of and for the years ended December 31, 2019 and 2018.
99.3*	Unaudited pro forma condensed combined balance sheet as of December 31, 2019 and unaudited combined condensed statement of operations for the year ended December 31, 2019.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
*	Filed herewith.
#	Indicates management contract or compensatory plan.
†	The schedules and exhibits to the merger agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.
+	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 SEC upon request. Certain confidential portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K. Copies of the unredacted exhibit will be furnished to the SEC upon request.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 29, 2020

LUMOS PHARMA, INC.,
a Delaware corporation

By: /s/ Richard J. Hawkins
Richard J. Hawkins
Chief Executive Officer

Exhibit 10.6

Certain identified information in this document has been excluded because it is both (i) not material and (ii) would likely cause competitive harm if publicly disclosed. [***] indicates where such information has been omitted.

LICENSE AGREEMENT

by and between

MERCK SHARP & DOHME CORP.

and

AMMONETT PHARMA LLC

THIS EXCLUSIVE LICENSE AGREEMENT (this "Agreement"), effective as of October 22, 2013 (the "Effective Date"), is by and between MERCK SHARP & DOHME CORP., a corporation organized and existing under the laws of New Jersey ("Merck"), and AMMONETT PHARMA LLC, a corporation organized and existing under the laws of Delaware (hereinafter referred to as "Licensee"). Merck and Licensee are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

WHEREAS, Merck has discovered and developed the drug MK-0677 and Merck is seeking a licensee to further develop and commercialize MK-0677;

WHEREAS, Licensee desires to develop and commercialize MK-0677; and

WHEREAS, Licensee and Merck desire to enter into a license arrangement whereby Licensee will develop and commercialize MK-0677.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, Licensee and Merck hereby agree as follows:

ARTICLE I - DEFINITIONS

As used in this Agreement, the following capitalized terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.01 "**Affiliate**" shall mean any individual or entity directly or indirectly controlling, controlled by or under common control with a Party to this Agreement. For purposes of this Agreement, the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of an entity, or the right to receive fifty percent (50%) or more of the profits or earnings of an entity shall be deemed to constitute control. Such other relationship as in fact results in actual control over the management, business and affairs of an entity shall also be deemed to constitute control.

1.02 "**Calendar Quarter**" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31, for so long as this Agreement is in effect; provided, however, that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end upon the expiration of this Agreement.

1.03 "**Calendar Year**" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31, for so long as this Agreement is in effect; provided, however, that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31, 2013 and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

1.04 "**Clinical Trial**" shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, Phase IIIb Clinical Trial and/or post-approval clinical trial.

1.05 "**Combination Product**" shall mean Licensed Product which includes one or more active ingredients other than Licensed Compound in combination with Licensed Compound. All references to Licensed Product in this Agreement shall be deemed to include Combination Product.

1.06 "**Commercialization**" **or** "**Commercialize**" shall mean, with respect to Licensed Compound or Licensed Product, any and all activities directed to the marketing, promotion, distribution, offering for sale and selling such product, importing and exporting such product for sale, and interacting with Regulatory Authorities regarding the foregoing. Commercialization shall also include Commercialization Studies.

1.07 "**Commercialization Studies**" shall mean a study or data collection effort for Licensed Product that is initiated in the Territory after receipt of Marketing Authorization for Licensed Product and is principally intended to support the Commercialization of Licensed Product in the Territory; provided, that such study or data collection effort is not principally to support or maintain a Marketing Authorization or obtain a label change or maintain a label.

1.08 "**Compound Patent Rights**" shall mean those patents and patent applications that as of the Effective Date are owned or controlled by Merck (and/or any of its Affiliates) and are listed on Schedule 1.8, that (A) have claims specifically covering Licensed Compound or the Manufacture and/or use thereof; (B) are substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, certificates of invention, confirmations, re-examinations, extensions, supplementary protection certificates or the like, or the provisional applications of any such patents and patent applications; or (C) are foreign equivalents of any of the above.

1.09 "**Development**" **or** "**Develop**" shall mean all preclinical research and development activities and all clinical drug development activities, including, among other things: drug discovery, toxicology, formulation, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining and maintaining Marketing Authorization (including without limitation, post-marketing studies), and regulatory affairs related to all of the foregoing. Development shall include all clinical studies (including Phase III-B) that are primarily intended to support or maintain a Marketing Authorization, maintain a label or obtain any label change, but shall exclude Commercialization Studies.

1.10 "**Development or Commercial Arrangement**" shall mean a license, distributorship, co-marketing or co-promotion arrangement to research, develop, commercialize, manufacture, have manufactured, use, import, export, sell and/or offer to sell Licensed Product in the Field in at least one of the United States, a Major European Country or Japan; *provided*, *however*, that a Development or Commercial Arrangement with a Third Party shall not include: (i) any agreement with a contractor, contract research organization, contract manufacturer or other Third Party, under which such Third Party performs contract services on behalf of Licensee or its Affiliates, (ii) an assignment by the Licensee of the Agreement and its rights and obligations hereunder to an Affiliate or in connection with the transfer or sale of all or substantially all of its assets related to the division or the subject business, or in the event of its merger or consolidation or change in control or similar transaction described in Section 14.01(a) or (iii) a Change of Control.

1.11 "**Diligent Efforts**" shall mean the performance of obligations or tasks in a continuous, sustained manner consistent with the reasonable best practices of the pharmaceutical industry for the development or commercialization of a product having similar technical and regulatory factors and similar market potential, profit potential and strategic value, and that is at a similar stage in its development or product life cycle, in each case based on conditions then prevailing and without regard to any competitive internal program of Licensee. Diligent Efforts requires that the Party (a) promptly assign responsibility for such obligations to specific employees who are held accountable for progress and monitoring such progress on an ongoing basis, (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations, and (c) consistently make and implement decisions and allocate adequate resources designed to advance progress with respect to such obligations.

1.12 "**Field**" shall mean the use of Licensed Compound or Licensed Product to treat or prevent any disease, disorder or conditions in human, excluding Autism Spectrum Disorders as defined in the Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders.

1.13 "**First Commercial Sale**" shall mean, with respect to a country in the Territory, the first shipment of commercial quantities to a Third Party of a Licensed Product sold in such country to a Third Party on arm's length terms by Licensee, its Affiliate or sublicensee for use in the Field after the receipt of Marketing Authorization in such country. Sales for test marketing, sampling and promotional uses, Clinical Trial purposes or compassionate or similar use shall not be considered to constitute a First Commercial Sale.

1.14 "**Good Clinical Practices**" shall mean the then current Good Clinical Practices as such term is defined from time to time by the United States Food and Drug Administration ("FDA") or other relevant governmental authority having jurisdiction over the Development, Manufacture or sale of Licensed Product in the Territory pursuant to its regulations, guidelines or otherwise.

1.15 "**Good Laboratory Practices**" shall mean the current good laboratory practice regulations of the FDA as described in the United States Code of Federal Regulations ("CFR") or any comparable corresponding foreign regulations or their respective successor regulations.

1.16 "**Good Manufacturing Practices**"shall mean the then current Good Manufacturing Practices as such term is defined from time to time by the FDA or other relevant governmental authority having jurisdiction over the Development, manufacture or sale of Licensed Product in the Territory pursuant to its regulations, guidelines or otherwise.

1.17 "**IND**"shall mean an investigational new drug application with respect to Licensed Product filed with the FDA for beginning clinical trials in humans, or any comparable application filed with the Regulatory Authorities of a country other than the United States prior to beginning clinical trials in humans in that country, as well as all supplements or amendments filed with respect to such filings.

[***] Indicates that information has been omitted.

1.18 "**Know-How**" shall mean proprietary information and materials (whether patentable or not) related to Licensed Compound, Licensed Product, any Combination Product, formulation, product improvement and/or indication, or the Manufacture or use of any of the foregoing, that are not in the public domain, including, without limitation, (a) ideas, discoveries, inventions, improvements, technology or trade secrets, (b) pharmaceutical, chemical and biological materials, products, components or compositions, (c) methods, procedures, formulas, processes, tests, assays, techniques, regulatory requirements and strategies, (d) biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, Manufacturing and quality control data and information related thereto, (e) technical and non-technical data and other information related to the foregoing, (f) drawings, plans, designs, diagrams, sketches, specifications or other documents containing or relating to such information or materials and (g) all applications, registrations, licenses, authorizations, approvals and correspondence relating to Licensed Compound and/or Licensed Product submitted to Regulatory Authorities.

1.19 "**Licensee**" shall have the meaning given to such term in the preamble of this Agreement.

1.20 "**Licensee Know-How**"shall mean Know-How developed by Licensee and/or any of its Affiliates or sublicensees after the Effective Date.

1.21 "**Licensee Patent Rights**" shall mean any and all patents and patent applications that after the Effective Date are owned or controlled by Licensee (and/or any of its Affiliates) that (A) have claims covering: (i) Licensed Compound or the Manufacture and/or use thereof, or (ii) Licensed Product or the Manufacture and/or use thereof; (B) arc substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, certificates of invention, confirmations, re-examinations, extensions, supplementary protection certificates or the like, or the provisional applications of any such patents and patent applications; or (C) are foreign equivalents of any of the above.

1.22 "**Licensed Compound**" shall mean:

(i) the Merck compound known as ibutamoren or MK-0677 with the following chemical name:

N-[1(*R*)-[(1,2-dihydro-l-methanesulfonylspiro[3H-indole-3,4'-piperidin]-1'-yl)carbony1]-2-(phenylmethyloxy)ethyl]-2-amino-2-methylpropanamide,

and/or

(ii) **[***]**;

including any pharmaceutically acceptable salt, polymorph, crystal form, prodrug or solvate of (i) or (ii).

1.23 "**Licensed Product**" shall mean any pharmaceutical composition, dosage form or preparation, including, without limitation, a Combination Product, which contains as an active ingredient Licensed Compound.

1.24 "**Major European Country**" shall mean any of France, Germany, Italy, Spain or the United Kingdom.

1.25 "**Manufacture**" shall mean all activities related to the manufacturing of a pharmaceutical product, or any ingredient thereof, including but not limited to test method development and stability testing, formulation, process development, manufacturing for use in non-clinical or clinical studies, manufacturing scale-up, manufacturing Licensed Compound or Licensed Product quality assurance/quality control development, quality control testing (including in-process release and stability testing), packaging, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, and regulatory activities related to all of the foregoing.

1.26 "**Marketing Authorization**" shall mean all approvals from the relevant Regulatory Authority necessary to market and sell a Licensed Product in any country (including without limitation all applicable Price Approvals even if not legally required to sell Licensed Product in a country).

1.27 "**Merck**" shall have the meaning given to such term in the preamble to this Agreement.

1.28 "**Merck Know-How**" shall mean the Know-How owned or controlled by Merck and/or any of its Affiliates as of the Effective Date that was used by Merck or its Affiliates as of the Effective Date in the Development or Manufacture of Licensed Compound that is listed on Schedule 1.28 or is otherwise provided to Licensee by Merck under this Agreement.

1.29 "**NDA**" shall mean a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Application Authorization, filing pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act (the "Act") or similar application or submission for Marketing Authorization of a Product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.

1.30 "**Net Sales**" shall mean the gross invoice price (not including value added taxes, sales taxes, or similar taxes) of Licensed Product sold by Licensee or its Related Parties to the first Third Party after deducting, if not previously deducted, from the amount invoiced or received:

(a) trade and quantity discounts other than early payment cash discounts;

(b) returns, rebates, chargebacks and other allowances;

(c) retroactive price reductions that are actually allowed or granted;

(d) sales commissions paid to Third Party distributors and/or selling agents;

(e) a fixed amount equal to one percent (1%) of the amount invoiced to cover bad debt, early payment cash discounts, transportation and insurance and custom duties; and

(f) the standard inventory cost of devices or delivery systems used for dispensing or administering Product.

With respect to sales of Combination Products, Net Sales shall be calculated on the basis of the gross invoice price of Products(s) containing the same strength of Compound sold without other active ingredients. In the event that Product is sold only as a Combination Product, Net Sales shall be calculated on the basis of the gross invoice price of the Combination Product multiplied by a fraction, the numerator of which shall be the inventory cost of Compound in the Product and the denominator of which shall be the inventory cost of all of the active ingredients in the Combination Product. Inventory cost shall be determined in accordance with Licensee's regular accounting methods. Consistently applied. The deductions set forth in Sections 1.30 (a) through (e) will be applied in calculating Net Sales for a Combination Product. In the even that Product is sold only as a Combination Product and either Party reasonably believes that the calculation set forth in this Paragraph does not fairly reflect the value of the Product relative to the other active ingredients in the Combination Product, the Parties shall negotiate, in good faith. Other means of calculating Net Sales with respect to Combination Products.

1.31 "**Party**" **or** "**Parties**" shall have the meaning given to such term in the preamble to this Agreement.

1.32 "**Phase 1 Clinical Trial**" shall mean a clinical trial of a Licensed Product in human patients at single and multiple dose levels with the primary purpose of determining safety, metabolism, and pharmacokinetic and pharmacodynamic properties of such Licensed Product, and which is consistent with 21 U.S. CFR § 312.21 (a).

1.33 "**Phase II Clinical Trial**" shall mean a clinical trial of a Licensed Product in human patients, the principal purposes of which are to make a preliminary determination that Licensed Product is safe for its intended use, to determine its optimal dose, and to obtain sufficient information about such Licensed Product's efficacy to permit the design of Phase III Trials, and which is consistent with 21 U.S. CFR § 312.21(b).

1.34 "**Phase III Clinical Trial**" shall mean a clinical trial of a Licensed Product in human patients, which trial is designed (a) to establish that Licensed Product is safe and efficacious for its intended use, (b) to define warnings, precautions and adverse reactions that are associated with such Licensed Product in the dosage range to be prescribed, (c) to be, either by itself or together with one or more other Clinical Trials having a comparable design and size, the final human Clinical Trial in support of Marketing Authorization of such Licensed Product, and (d) consistent with 21 U.S. CFR § 312,21(c). "Phase III Trial" shall not include a Phase IIIb Trial.

1.35 "**Phase IIIb Clinical Trial**" shall mean a clinical trial of a Licensed Product in human patients, which provides for product support (i.e., a clinical trial which is not required for receipt of initial Marketing Authorization but which may be useful in providing additional drug profile data or in seeking a label expansion) commenced before receipt of Marketing Authorization for the indication for which such trial is being conducted.

1.36 "**Price Approval**" shall mean the approval or determination by a Regulatory Authority for the pricing or pricing reimbursement for a pharmaceutical products.

1.37 "**Proprietary Information**" shall mean, as applicable, Know-How and all other scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, verbally or electronically, that is provided by one Party to the other Party in connection with this Agreement.

1.38 "**Regulatory Authority**" shall mean any United States federal, state, or local government, or any foreign government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body with responsibility for granting licenses or approvals, including Marketing Authorizations, necessary for the marketing and sale of Licensed Product in any country.

1.39 "**Related Party**" shall mean each of Licensee, its Affiliates, and their respective sublicensees (which term does not include distributors), as applicable.

1.40 "**Territory**" shall mean the entire world.

1.41 "**Third Party**" shall mean an entity other than Merck and its Affiliates and Licensee and its Related Parties.

1.42 "**Valid Claim**"shall mean a claim of an issued and unexpired patent included within the Compound Patent Rights, that has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer.

1.43 **Additional Definitions**. Each of the following definitions is set forth in the Section of this Agreement indicated below.

Definition	Section
AAA	13.02(a)
Act	1.28
AEs	4.02(a)
Agents	9.01(b)
Agreement	Preamble
Annual Commercialization Report	3.04
CFR	1.14
Change of Control	14.01(c)
Contract Sales Force	3.05
Development Plan	3.02(a)
Effective Date	Preamble
FDA	1.13
Force Majeure	14.08
Inventory	4.01(b)
Liability	11.01

LIBOR	7.05(e)
Licensee Indemnified Party	11.02
Merck Indemnified Party	11.01
Merck Retained Rights	2.01
Option Notice	3.06(a)
Research Use	2.01(c)
Sublicense Agreement	2.05
Supply Agreement	6.02(a)
Supply Option	6.02(a)
Term	12.01

ARTICLE II - LICENSE

2.01 License Grant. Subject to the terms and conditions of this agreement and Merck's retained rights, Merck hereby grants the following to Licensee:

(a) Development License. A royalty bearing license in the Territory in the Field, with the right to grant sublicenses as provided herein, under the Compound Patent Rights, which Compound Patent Rights license shall be exclusive (even as to Merck and its Affiliates, except as provided in Section 2.01(c)) to Develop, Manufacture, have Manufactured, use, import, export and Commercialize Licensed Compound and Licensed Product in the Field in the Territory during the Term.

(b) Know-How License. A royalty bearing exclusive license in the Territory in the Field, with the right to grant sublicenses as provided herein, to Merck Know-How to Develop, Manufacture, have Manufactured, use, import, export and Commercialize Licensed Compound and Licensed Product in the Field in the Territory during the Term.

(c) Research License. A license, co-exclusive with Merck and its Affiliates, with the right to grant sublicenses as provided herein, under the Compound Patent Rights and Merck Know-How to research, make, have made, use, and import Licensed Compound and Licensed Product in the Field in the Territory during the Term for research use ("Research Use"). Research Use does not include any right to Commercialize Licensed Compound or Licensed Product in the Field.

For the avoidance of doubt, Merck retains all rights not granted herein, including the Research Use right, to all Compound Patent Rights and Merck Know-How including Licensed Compound and Licensed Product for the Term ("Merck Retained Rights").

2.02 Non-Exclusive License Grant. Merck hereby grants to Licensee a non-exclusive license in the Territory in the Field to any patent applications or patents owned or controlled by Merck that result from the exercise of its Research License under Section 2.01(c), but only to the extent said patent applications or patents (i) have claims specifically and solely covering Licensed Compound and/or the Manufacture and/or use thereof and (ii) are reasonably necessary by Licensee for the Development or Commercialization of Licensed Compound as contemplated in the Development Plan, said non-exclusive license to Develop, Manufacture, have Manufactured, use, import, export and Commercialize Licensed Compound in the Field in the Territory during the Term in accordance with the Development Plan.

2.03 No Non-Permitted Use. Licensee hereby covenants that it shall not, nor shall it cause or permit any Affiliate or sublicensee to knowingly, use or practice, directly or indirectly, any Merck Know-How or Compound Patent Rights for any purposes other than those expressly permitted by this Agreement.

2.04 No Other Licenses. Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel, or otherwise, other than the license rights that are expressly granted under this Agreement.

2.05 Right to Sublicense and Sublicense Agreements. The licenses granted in this Section 2.01 may be sublicensed by Licensee to (a) an Affiliate, (b) a Third Party for any country in the Territory other than the U.S., the Major European Countries and Japan without the consent of Merck; and (c) a Third Party for the U.S., Major European Countries and Japan with the prior written consent of Merck, not to be unreasonably withheld. Licensee shall, in each agreement under which it grants a sublicense under the licenses set forth in Section 2.01 (each, a "Sublicense Agreement"), require the sublicensee to transfer to Merck, if this Agreement terminates, and to Licensee, if only such sublicense terminates, (a) all regulatory filings and Marketing Authorizations held, possessed or controlled by such sublicensee and (b) all patent rights and Know-How controlled by such sublicensee relating to Licensed Compound or Licensed Product or its use, Manufacture, sale, or importation (such patent rights and Know-How shall be transferred either by (i) assignment, or by a freely sublicensable exclusive license, in the case of patent rights and Know-How related solely to Licensed Compound or Licensed Product, or (ii) by a non-exclusive license in the case of patent rights and Know-How that are related to patents or products other than Licensed Compound or Licensed Product). Any sublicense agreement shall be consistent with the terms and conditions of this Agreement, and without limiting the foregoing, shall include the following provisions for the benefit of Merck:

(a) must require the sublicensee to abide by confidentiality and non-use obligations at least as stringent as those contained in Article IX of this Agreement;

(b) must include rights and obligations upon termination of the sublicense which are consistent in all material respects with the termination provisions of this Agreement;

(c) in the event that the sublicensee is granted the right to offer to sell or sell Licensed Compound or Licensed Product, must require the sublicensee to pay at least the royalties on Net Sales of Licensed Product specified in Article VII of this Agreement and to keep records and render reports as required in Section 7.04 and Section 7.05 and be subject to Merck's audit rights as set forth in Section 7.05 of this Agreement;

(d) must preclude the sublicensee from granting further sublicenses or the right to enforce the Compound Patent Rights;

(e) must obligate the sublicensee to maintain insurance in amounts consistent with Section 11.06;

(f) must provide an indemnity from the sublicensee in favor of Merck and Merck Indemnified Party to the same extent as the indemnity contained in Section 11.01, and must provide that the sublicensee agrees that it will not challenge the standing of Merck if it seeks to rely on such indemnification; and

(g) must include a provision stating, in words or substance, that Merck is not a party to the sublicense agreement and has no liability to any licensee, sublicensee or user of anything covered by the sublicense agreement, but that Merck is an intended third party beneficiary of the sublicense agreement and certain of its provisions are for the benefit of Merck and are enforceable by Merck in its own name.

Licensee shall (i) use reasonable efforts to procure the performance by any sublicensee of the terms of each such sublicense Agreement, and (ii) ensure that any sublicensee will comply with the applicable terms and conditions of this Agreement. Licensee hereby guarantees the performance of its Affiliates and sublicensees that are sublicensed as permitted herein, and the grant of any such sublicense will not relieve Licensee of its obligations under this Agreement, except to the extent they are satisfactorily performed by such Affiliate or sublicensee.

2.06 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. Each Party shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code or equivalent legislation in any other jurisdiction. Upon the bankruptcy of either Party, the other Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to such other Party, unless the Party in bankruptcy elects to continue, and continues, to perform all of its obligations under this Agreement.

ARTICLE III - DEVELOPMENT AND COMMERCIALIZATION

3.01 Overview. As of the Effective Date, Licensee shall be solely responsible for the Development and Commercialization, including all costs thereof, of Licensed Product in the Field in the Territory. Licensee shall perform all of its Development activities in accordance with an IND for Licensed Product and with all applicable laws, rules and regulations.

3.02 Development and Commercialization Plans.

(a) Initial Development Plan. Not later than the Effective Date, the Parties shall have agreed on the initial Development plan for Licensed Product in the Field in the Territory, which shall be incorporated as part of this Agreement as Schedule 3.02(a) (as may be amended in accordance with this Agreement, the "Development Plan").

(b) **Annual Development Plan**. Not later than thirty (30) days after December 31 of each Calendar Year, Licensee shall submit to Merck an updated Development Plan for the pending Calendar Year. Such update shall take into account completion, commencement, changes in or cessation of Development activities not contemplated by the then-current Development Plan sufficient to reflect that Diligent Efforts are being undertaken by Licensee with respect to Licensed Compound. The updated Development Plan shall also describe Licensee's progress with respect to its Development efforts under this Agreement and shall include the following information for Licensed Product: a description of the Development work to be conducted during the year in reasonable detail, including clinical studies, formulation work, manufacturing work, other testing work and regulatory activity; timelines for such work; and key decision gates and milestones for such work. Merck shall have the right to comment on such annual plan. In the event Merck reasonably disagrees with the plan, Licensee shall consider Merck's comments for revising the plan. At Merck's written request, the President of Merck's research division, or his designee, and the President of Licensee's research division or equivalent position, or his designee, shall meet to discuss such comments and, if Licensee so chooses, the changes can be incorporated into a revised annual Development Plan. Any revision of the annual plan shall be submitted to Merck promptly after its completion.

(c) **Performance**. Licensee shall perform, and shall ensure that its Affiliates, sublicensees, and Third Party contractors perform, the activities described in the Development Plan in a professional manner and in compliance with, to the extent applicable, Good Laboratory Practices, Good Clinical Practices and/or Good Manufacturing Practices and in compliance with all other applicable laws, rules, and regulations.

(d) The Development Plans provided to Merck shall constitute Proprietary Information of Licensee subject to Article X.

3.03 **Commercialization**. Licensee shall give Merck prior written notice of at least sixty (60) days of its intent to file an NDA for Licensed Product and at that time shall further provide Merck with the non-binding anticipated date of First Commercial Sale for Licensed Product in the country of filing based on best information available at the time. Licensee shall promptly provide Merck with notice of any Marketing Authorization of Licensed Product.

3.04 **Commercialization Reports**. Commencing with the First Commercial Sale and thereafter on an annual basis, Licensee shall provide Merck with a written non-binding estimate of annual Net Sales for Licensed Product in the Territory ("Annual Commercialization Report"). The Annual Commercialization Report shall also list all ongoing Commercialization Studies and the status of such studies in the United States, the Major European Countries and Japan.

3.05 **Contract Sales Force**. Licensee shall not use the services of sales representatives employed by a Third Party as a contract sales force for Licensed Product ("Contract Sales Force") without the prior written consent of Merck, such consent not to be unreasonably withheld.

3.06 **Merck Option**. In addition to the rights granted by Licensee to Merck in Section 2.01. Licensee grants to Merck the option to evaluate Licensed Product and propose terms for a Development or Commercial Arrangement with respect to the Licensed Product in the Field on the following terms:

(a) Licensee shall notify Merck, in advance, in writing if at any time during the Term, Licensee intends to enter into a Development or Commercial Arrangement with a Third Party ("Option Notice").

(b) In the event that Merck notifies Licensee within 10 days after the delivery of the Option Notice that Merck intends to propose terms for a Development or Commercial Arrangement between the Parties, Licensee shall provide Merck with reasonable access to due diligence information customarily provided in the evaluation of similar Development or Commercial Arrangements. No later than 45 days after the delivery of the Option Notice, Merck shall, at its sole discretion, submit terms for a Development or Commercial Arrangement and if such terms are satisfactory to Licensee, after Licensee considers them in good faith, the Parties will negotiate in good faith for a period of sixty (60) days from Merck's submission of its terms to enter into a definitive agreement for such Development or Commercial Arrangement.

ARTICLE IV - REGULATORY; MATERIALS AND INFORMATION TRANSFER

4.01 Materials and Regulatory Filings Transfer.

(a) As soon as is reasonably practicable following the Effective Date of this Agreement, but in any event no later than forty-five (45) days after the Effective Date, Merck shall transfer to Licensee the Merck Know-How listed in Schedule 1.28 in single copy in electronic format only. Merck shall be responsible for all costs associated with transfer of Merck Know-How.

(b) As soon as is reasonably practicable following the Effective Date of this Agreement, Merck shall transfer to Licensee, in a mutually agreed manner, the quantities of physical inventory ("Inventory") of Licensed Compound in Merck's possession solely as listed in Schedule 4.01(b) and shall inform Licensee in writing as to the quantities of such Inventory that are in compliance with Good Manufacturing Practices following Merck's recertification of such Inventory; provided that the quantities listed are general guidance estimates only of the amounts currently anticipated to be available for shipping from Merck. Merck shall have no further obligation to make any further Licensed Compound(s) available to Licensee. Consistent with the license grant in Section 2.01, such Inventory shall only be used for clinical or commercial purposes to the extent that such Inventory was recertified by Merck as compliant with Good Manufacturing Practices; otherwise, such Inventory shall only be used in preclinical work in accordance with the license grant is Section 2.01.

(c) As soon as is reasonably practicable after the Effective Date (or such other date as may be mutually agreed by the Parties), Merck shall transfer to Licensee in electronic format the existing INDs and other drug approval applications listed in Schedule 1.28 covering Licensed Product. All further submissions to any Regulatory Authorities relating to such drug approval applications and/or INDs shall be filed in the name of and owned by Licensee or its Affiliates. Licensee or its Affiliates shall hold all Marketing Authorizations for Licensed Product throughout the Territory.

(d) As soon as is reasonably practicable after the Effective Date (or such other date as mutually agreed by the Parties), Merck shall transfer to Licensee one (1) copy of the material documents and records that have been generated by or on behalf of Merck with respect to any existing INDs and other drug approval applications covering Licensed Product in the Territory, as well as any material correspondence between Merck and Regulatory Authorities related to Licensed Product, solely to the extent listed on Schedule 1.28.

(e) Licensee shall oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to, the FDA and other Regulatory Authorities in the Territory with respect to Licensed Product.

(f) Licensee shall be solely responsible for interfacing, corresponding and meeting with the FDA and other Regulatory Authorities throughout the Territory with respect to Licensed Product. Licensee shall provide Merck with copies of any material correspondence with FDA or other Regulatory Authorities in the United States, the Major European Countries and Japan relating to approval of Licensed Product, and respond to all reasonable inquiries by Merck with respect thereto. Licensee shall also provide Merck in a timely manner with meeting minutes from any material meetings with Regulatory Authorities in the United States, the Major European Countries and Japan concerning the approval of Licensed Product.

(g) Licensee shall provide to Merck a table report on an annual basis that contains the status of Marketing Authorizations for Licensed Product in the Territory.

(h) In the event that any Regulatory Authority (a) threatens or initiates any action to remove a Licensed Product from the market in any country in the Field in the Territory after a Marketing Authorization has been issued in such country or (b) requires Licensee, its Affiliates, or its sublicensees to distribute a "Dear Doctor" letter or its equivalent regarding use of Licensed Product in the Field, Licensee shall notify Merck of such event within one (1) business day after Licensee becomes aware of the action, threat, or requirement (as applicable). Licensee shall consult with Merck prior to initiating a recall or withdrawal of Licensed Product in the U.S., Japan, or a Major European Country; provided, however, that the final decision as to whether to recall or withdraw a Licensed Product in the Territory shall be made by Licensee in its sole discretion. Licensee shall be responsible, at its sole expense, for conducting any recalls or taking such other necessary remedial action.

(i) Other than as set forth in Section 4.01(j), Merck shall have no obligation under this Section 4.01 to provide additional Merck Know-How to Licensee that is not specifically listed in Schedule 1.28, additional Inventory of Licensed Compound that is not listed in Schedule 4.01(b), or to provide any technical, regulatory or other advice or assistance. Merck shall retain the Inventory of Licensed Compound in Merck's possession that is not listed in Schedule 4.01(b), which may be used by Merck pursuant to the Merck Retained Rights under Section 2.01. For the avoidance of doubt, Merck shall have no obligation to provide the source documentation or any additional data, in any form, other than that provided within the Merck Know-How as listed in Schedule 1.28, or to provide information on patent searches, competitive analyses, market assessments, financial projections and/or strategies relating to Licensed Compound or Licensed Product.

(j) Merck agrees, at the reasonable request of Licensee, to provide Licensee with technical, regulatory or other advice or assistance, and to reasonably cooperate with Licensee in connection with the transfer of regulatory filings relating to Licensed Compound or Licensed Product. It is the intent of the Parties that Merck's obligation under this Section 4.01(j) shall extend no longer than nine (9) months after the Effective Date, after which date, Merck shall have no obligation under this Section 4.01, though Merck may at its sole discretion provide such advice or assistance beyond this date.

4.02 Pharmacovigilance.

(a) Following the transfer of any INDs related to Licensed Product from Merck to Licensee, Licensee shall be solely responsible for the collection, review, assessment, tracking and filing of information related to adverse events ("AEs") associated with each Licensed Product in the Field, in accordance with 21 CFR 312.32, 314.80 and comparable regulations, guidance, directives and the like governing AEs associated with Licensed Product that are applicable outside of the United States.

(b) Licensee shall assume responsibility for maintaining a global safety database for Licensed Product consistent with industry practices.

ARTICLE V - DILIGENCE

5.01 Generally. Licensee shall use Diligent Efforts to Develop and Commercialize Licensed Product in the Field in the United States, a Major European Country or Japan.

5.02 Specific Obligations. Without limiting the generality of Section 5.01, Licensee shall (a) within twelve (12) months after the Effective Date, submit to Merck for review and consideration a non-binding update to the Development Plan proposing activities for the Development of Licensed Product, and (b) undertake the commercial launch of any Licensed Product in a country promptly after, and in any case not later than nine (9) months after, the date that Marketing Authorization is granted with respect to such country.

5.03 Failure. In the event Licensee fails, in Merck's determination, to comply with the obligations set forth in this Article V, Merck shall furnish Licensee with Notice of such determination. Within ninety (90) days after receipt of such Notice, Licensee shall either (i) fulfill the relevant obligation or (ii) negotiate with Merck a mutually acceptable schedule of revised diligence obligations, failing which Merck shall have the right to exercise its termination rights under Article XII.

ARTICLE VI - MANUFACTURING TECHNOLOGY TRANSFER

6.01 Manufacturing Responsibility. Licensee will be responsible for the manufacturing of Licensed Compound and Licensed Product for use by Licensee, its Affiliates, and its sublicensees in the Field in the Territory.

[***] Indicates that information has been omitted.

6.02 Supply Option Grant.

(a) In further consideration of the license granted to Licensee hereunder, Licensee hereby grants to Merck an option to enter into a supply agreement with Licensee ("Supply Agreement") pursuant to which Licensee or a Related Party will supply Licensed Compound or Licensed Product to Merck for use under the Merck Retained Rights pursuant to Section 2.01 ("Supply Option"). Merck shall have the right to exercise the Supply Option by providing written notice to Licensee at any time during the Term. Promptly following such notice, the Parties shall proceed in good faith to negotiate and execute a Supply Agreement for the supply of a specified amount of Licensed Compound or Licensed Product. The Parties shall have a period of three (3) months after the date on which Licensee receives notice of Merck exercising the Supply Option, in which to finalize and execute the Supply Agreement, which may be extended upon mutual written agreement of the Parties.

(b) The Supply Agreement shall include the following terms: (i) the specific amount of Licensed Compound or Licensed Product, which shall be no more than 2 kg of Licensed Compound or 15,000 units of Licensed Product, (ii) Licensed Compound or Licensed Product shall be supplied to Merck at cost, and (iii) use of Licensed Compound or Licensed Product shall be permitted by Merck, its Affiliates or a Third Party under an agreement with Merck or its Affiliate, all in accordance with the Merck Retained Rights as set forth in Section 2.01 of this Agreement. Otherwise, the Supply Agreement shall contain the usual and typical clauses for such an agreement to be negotiated by the Parties.

(c) Merck shall have the right to exercise the Supply Option a total number of five (5) times.

ARTICLE VII - PAYMENTS; ROYALTIES AND REPORTS

7.01 Consideration for License. In consideration for the license granted to Licensee hereunder, Licensee shall pay to Merck a non-refundable, non-creditable, upfront payment of **[***]**, which shall be due within thirty (30) days of the Effective Date.

7.02 Milestone Payments. Subject to the terms and conditions of this Agreement and in further consideration for the license granted herein, licensee shall make each of the following one-time, non-refundable, non-creditable milestone payments to Merck based on attainment of the Development, regulatory and commercial milestones indicated below:

[***] Indicates that information has been omitted.

Development Milestones		
Development Milestones	**[***]**	
	[***]	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]		

Sales Milestone	
Sales Milestone	**[***]**
[***]	**[***]**
[***]	**[***]**
[***]	**[***]**

Licensee shall notify Merck in writing within ten (10) business days after the achievement of each such milestone event giving rise to a payment obligation under this Section and Licensee shall pay Merck the indicated amount no later than thirty (30) days after such notification to Merck.

[***] Indicates that information has been omitted.

7.03 Royalties.

(a) **Royalty Rates**. Subject to the terms and conditions of this Agreement, Licensee shall pay to Merck royalties on Net Sales of Licensed Products on a country-by-country basis in an amount equal to **[***]**. Notwithstanding the foregoing, in the event a generic version of a Licensed Product achieves **[***]** of total gross sales of Licensed Products in a particular country (as stated in IMS reports, for example in the United States, and in an analogous reports in other countries), the royalties payable to Merck under this Section 7.03(a) shall be reduced to **[***]** on Net Sales of Licensed Products in that particular country, for such time that the generic version of Licensed Product maintains **[***]** total gross sales of Licensed Products tit in that particular country.

(b) **Term of Royalty Obligation**. Royalties on Licensed Product shall commence upon the First Commercial Sale of a Licensed Product in a particular country in the Territory and will continue on a product-by-product, country-by-country basis until the later of (i) the expiration of the last to expire Valid Claim covering a Licensed Product in such country or (ii) the expiration of regulatory exclusivity for Licensed Product in such country or (iii) **[***]**.

7.04 Reports; Payment of Royalty; Payment Exchange Rate and Currency Conversions.

(a) **Royalties Paid Quarterly**. Within **[***]** following the end of each Calendar Quarter, following the First Commercial Sale of a Licensed Product, Licensee shall furnish to Merck a written report for the Calendar Quarter showing the Net Sales of Licensed Product sold by Licensee, its Affiliates and its sublicensees in the Territory during such Calendar Quarter and the royalties payable under this Agreement for such Calendar Quarter. Such written report shall include the gross sales of Licensed Product on a country-by-country basis, an itemized calculation of any deductions taken from such gross sales to arrive at Net Sales for the applicable Calendar Quarter and the calculation of the amount of royalty payment due on such Net Sales. Such report shall also include, on a country-by-country basis, the month and year of the first commercial sale of Licensed Product. Simultaneously with the submission of the written report, Licensee shall pay to Merck, for the account of Licensee or the applicable Affiliate or sublicensee, as the case may be, a sum equal to the aggregate royalty due for such Calendar Quarter calculated in accordance with this Agreement.

(b) **Method of Payment**. All payments to be made by Licensee to Merck under this Agreement shall be paid by bank wire transfer in immediately available funds to such bank account as is designated in writing by Merck from time to time. Royalty payments shall be made in United States dollars to the extent that free conversion to United States dollars is permitted. The rate of exchange to be used in any such conversion from the currency in the country where such Net Sales are made shall be the rate of exchange used by Licensee for reporting such sales for United States financial statement purposes. If, due to restrictions or prohibitions imposed by national or international authority, payments cannot be made as aforesaid, the Parties shall consult with a view to finding a prompt and acceptable solution, and Licensee will make such payments in any manner as Merck may lawfully direct; ,provided that Licensee shall not be obligated to incur any additional out-of-pocket expenses in connection with such payments. Notwithstanding the foregoing, if royalties in any country cannot be remitted to Merck for any reason within six (6) months after the end of the Calendar Quarter during which they arc earned, then Licensee shall be obligated to deposit the royalties in a bank account in such country in the name of Merck.

[***] Indicates that information has been omitted.

7.05 Maintenance of Records; Audits.

(a) **Record Keeping by Licensee**. Licensee and its Affiliates shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined. Upon sixty (60) days prior written notice from Merck, Licensee shall permit an independent certified public accounting firm of nationally recognized standing selected by Merck and reasonably acceptable to Licensee, at Merck's expense, to have access during normal business hours to examine the pertinent books and records of Licensee, its Affiliates and/or sublicensees as may be reasonably necessary to verify the accuracy of the royalty reports hereunder. The examination shall be limited to the pertinent books and records for any year ending not more than thirty-six (36) months prior to the date of such request. Historical records will not be requested from Licensee for any periods prior to the Effective Date of this Agreement. An examination under this Section 7.05(a) shall not occur more than once in any Calendar Year. Licensee may designate competitively sensitive information that such auditor may not disclose to Merck, provided, however. that such designation shall not encompass the auditor's conclusions. The accounting firm shall disclose to Merck only whether the royalty reports arc correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to Merck. All such accounting firms shall sign a confidentiality agreement (in form and substance reasonably acceptable to Licensee) as to any of Licensee's or its Affiliate's confidential information that such accounting firms are provided, or to which they have access, while conducting any audit pursuant to this Section 7.05(a).

(b) **Underpayments/Overpayments**. If such accounting firm correctly concludes that additional royalties were owed during such period, Licensee shall pay such additional royalties within thirty (30) days of the date Merck delivers to Licensee such accounting firm's written report so correctly concluding. If such underpayment exceeds Two Hundred Fifty Thousand Dollars and five percent (5%) of the sums correctly due Merck then the fees charged by such accounting firm for the work associated with the underpayment audit shall be paid by Licensee. Any overpayments by Licensee will be credited against future royalty obligations.

(c) **Record Keeping by Sublicensee**. Licensee shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the sublicensee to make reports to Licensee, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by Merck's independent accountant to the same extent required of Licensee under this Agreement.

(d) **Confidentiality**. Merck shall treat all financial information subject to review under this Section 7.05, or under any sublicense agreement, in accordance with the confidentiality

provisions of Article IX of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with Licensee obligating it to retain all such financial information in confidence pursuant to such confidentiality agreement.

(e) **[***]**.

ARTICLE VIII - PATENTS

8.01 Prosecution and Maintenance of Patents. Merck agrees to prosecute and maintain in the Territory, on its own or through mutually agreeable outside counsel, the Compound Patent Rights, provided that Licensee will reimburse Merck for its out-of-pocket expenses, including legal fees, relating to such patent prosecution and maintenance in all countries. Merck shall keep Licensee advised of such patent prosecution and maintenance and upon the written request of the Licensee, will provide advance copies of any substantive papers related to the prosecution and maintenance of such patent filings. A budget estimate of total patent costs to the best estimate of Merck will be provided to Licensee within sixty (60) days of after the Effective Date.

8.02 Option of Licensee to Prosecute and Maintain Patents. Merck shall give notice to Licensee of any desire to cease prosecution and/or maintenance of any patent application or patent included in the Compound Patent Rights and, in such case, shall permit Licensee, at Licensee's sole discretion, to continue the prosecution or maintenance of the Compound Patent Rights in Merck's name at the expense of Licensee.

8.03 Enforcement and Defense. In the event that either Licensee or Merck becomes aware of any alleged, threatened or actual commercially material infringement of a Compound Patent Right in a country in the Territory, or judicial challenge to the validity of a Compound Patent Right in a country in the Territory, it will notify the other Party in writing to that effect within a reasonable time period. Merck and Licensee shall thereafter consult and cooperate fully to determine a course of action, including but not limited to the commencement of legal action by either or both Merck and Licensee to terminate any infringement of Compound Patent Rights or defend the validity of any Compound Patent Right. In all instances, each Party shall have the right to be represented by counsel of its own choice.

(a) First Right of Merck; Right of Licensee to Assume. Merck shall have the first right to initiate, prosecute or control any such legal action. Merck shall promptly notify Licensee in writing if it elects not to exercise such first right and, if the rights of Licensee under this Agreement may be materially affected, Licensee shall thereafter have the right to either initiate, prosecute or control, entirely under its own direction, any such legal action, in the name of Licensee and, if necessary, Merck.

[***] Indicates that information has been omitted.

(b) Expenses and Cooperation. Merck shall bear all the expenses of any legal action brought by it and in which Licensee is not a party to the action. Licensee shall have the right, prior to commencement of the legal action brought by Merck, to join any such legal action in which the rights of Licensee under this Agreement may be materially affected. In the event that Licensee joins in such legal action, or initiates, prosecutes or controls the defense of any such action pursuant to Section 8.03(a), Licensee shall pay the costs of such legal action. Each Party shall keep the other informed of developments in any action or proceeding, including, to the extent permissible by law, the consultation and approval of any settlement negotiations and the terms of any offer related thereto. In the event that Licensee is a party to such a legal action, no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the mutual consent of Licensee and Merck, and such consent shall not be unreasonably withheld.

(c) Recovery. **[***]**.

8.04 Patent Term Restoration. The Parties hereto shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Compound Patent Rights. In the event there is a conflict between Merck and Licensee with respect to an election for obtaining such patent term restoration or supplemental protection certificates or their equivalents, Merck shall have the right to make the election and Licensee agrees to abide by such election. Each Party agrees to assist the other Party as needed with the filing and prosecuting of any such application for patent term restoration or supplemental protection certificates or their equivalents. In the event Merck makes the election pursuant to its right under this Section 8.04. Merck shall pay all costs associated with the preparation, filing and prosecuting of any such application for patent term restoration or supplemental protection certificates or their equivalents; otherwise the cost will be borne by Licensee.

8.05 Interference, Derivation, Opposition, Reissue Reexamination and Post Grant Review Proceedings. Any Party shall, within ten (10) business days of learning of any request for, or filing or declaration of, any interference, derivation, opposition, reexamination, or post grant review (or similar administrative proceedings) relating to Compound Patent Rights, inform the other Party of such event. Merck and Licensee shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Merck shall have the first right to control any such proceeding or action. Merck shall promptly notify Licensee in writing if it elects not to exercise such first right and, if the rights of Licensee under this Agreement may be materially affected, Licensee shall thereafter have the right to control, entirely under its own direction, any such proceeding or action, in the name of Merck. The controlling Party shall bear the expense of such proceeding or action. The controlling Party shall keep the non-controlling Party informed of developments in any such action or proceeding, including, to the extent permissible by law, consultation and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

8.06 Abandonment. Merck shall promptly give notice to Licensee of the grant lapse, revocation, surrender, invalidation or abandonment of any Compound Patent Rights licensed to Licensee for which Merck is responsible for the prosecution and maintenance under this Agreement. If Merck declines to exercise its first right under Section 8.03 or Section 8.05, Merck shall have no obligation to initiate, prosecute or control any such legal action or proceeding.

8.07 No Challenge of Validity of Patent. Licensee hereby agrees that in the event that it, its Affiliates or sublicensees challenges the validity of any patent application or patent within the Compound Patent Rights, Merck may, in its sole discretion, exercise its termination rights under Article XII.

ARTICLE IX - CONFIDENTIALITY AND PUBLICATION

9.01 Confidentiality.

(a) **Nondisclosure Obligation**. Each of Merck and Licensee shall use any Proprietary Information received by it from the other Party only in accordance with this Agreement and shall not disclose to any Third Party any such Proprietary Information without the prior written consent of the other Party. The foregoing obligations shall survive the expiration or termination of this Agreement for a period of ten (10) years. These obligations shall not apply to Proprietary Information that:

(i) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's written records;

(ii) is at the time of disclosure or thereafter becomes, published or otherwise part of the public domain without breach of the obligation of confidentiality under this Agreement by the receiving Party;

(iii) is subsequently disclosed to the receiving Party by a Third Party who has the right to make such disclosure, as documented by the receiving Party's written records;

(iv) is independently developed by the receiving Party or its Affiliates and without the aid, use or application of any of the disclosing Party's Proprietary Information, and such independent development can be documented by the receiving Party's written records;

(v) is disclosed to any institutional review board of any entity conducting clinical trials with Licensed Product or to any governmental or other regulatory agencies in order to obtain patents or to gain approval to conduct clinical trials or to market Licensed Product, provided that such disclosure may be made only to the extent reasonably necessary to obtain such patents or authorizations; or

(vi) is required to be disclosed by law, regulation, rule, act or order of any governmental authority or agency to be disclosed, provided that notice is promptly delivered to the other Party in order to provide an opportunity to seek a protective order or other similar order with respect to such Proprietary Information and thereafter the receiving Party discloses to the requesting entity only the minimum information required to be disclosed in order to comply with the request, whether or not a protective order or other similar order is obtained by the other Party.

(b) **Disclosure to Agents**. Notwithstanding the provisions of Section 9.01(a) and subject to the other terms of this Agreement, each of Licensee and Merck shall have the right to disclose Proprietary Information to their respective sublicensees, agents, consultants, Affiliates or other Third Parties (collectively "Agents") in accordance with this Section 9.01(b). Such disclosure shall be limited only to those Agents directly involved in the Development, Manufacturing, marketing or promotion of Licensed Compound or Licensed Product (or for such Agents to determine their interest in performing such activities) in accordance with this Agreement. Any such Agents must agree in writing to be bound by confidentiality and non-use obligations essentially the same as those contained in this Agreement.

9.02 Return of Confidential Information. Upon termination of this Agreement, the receiving Party will return all documents, and copies thereof, including those in the possession of the receiving Party's Agents pursuant to Section 9.01(b), containing the disclosing Party's Proprietary Information at any time upon the written request of the disclosing Party. However, the receiving Party may retain one (1) copy of such documents in a secure location solely for the purposes of (i) determining its obligations hereunder, (ii) complying with any applicable regulatory requirements, or (iii) defending against any product liability claim.

9.03 Breach of Confidentiality. The Parties agree that the disclosure of the Disclosing Party's Proprietary Information in violation of this Agreement may cause the Disclosing Party irreparable harm and that any breach or threatened breach of this Agreement by the Receiving Party entitles disclosing Party to seek injunctive relief, in addition to any other legal or equitable remedies available to it, in any court of competent jurisdiction. For clarity, such disputes shall not be subject to Article XIII.

9.04 No Publicity. A Party may not use the name of the other Party in any publicity or advertising and may not issue a press release or otherwise publicize or disclose any information related to the existence of this Agreement or the terms or conditions herein, except (i) on the advice of its counsel as required by law (e.g., any Securities and Exchange Commission filings and disclosures) and provided the Party who will be disclosing such information has consulted with the other Party to the extent feasible prior to such disclosure with respect to the substance of the disclosure; or (ii) as consented to in advance by the other Party in writing. The Parties shall agree on a form of initial press release that may be used by either Party on an ongoing basis to describe this Agreement. Licensee shall provide Merck with reasonable advance written notice of any press release or other public disclosure of the results of any of its work on Licensed Product under this Agreement.

9.05 Scientific Publications. Each Party recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. Consequently, except for disclosures permitted pursuant to Section 9.01 and Section 9.04 of this Agreement, in the event that a Party wishes to make a publication containing any Merck Know-How or that is the subject of Compound Patent Rights, such Party shall deliver to the other Party a copy of the proposed written publication at least sixty (60) days prior to submission for publication. The Parties shall have the right to propose modifications to or delay of the publication for patent reasons or trade secrets. If a reviewing Party requests a delay for patent reasons, the other Party shall delay submission for a period of up to ninety (90) days to enable patent applications protecting each Party's rights in such information to be filed. Upon expiration of such delay, the Party seeking to publish shall be free to proceed with the publication. If a Party requests modifications to the publication, the Party seeking to publish shall edit such publication to prevent disclosure of trade secret or Proprietary Information prior to submission of the publication.

9.06 **Terms of Agreement**. Neither Party nor its Affiliates shall disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except as follows: A Party and its Affiliates may disclose the terms or conditions of this Agreement (but not any other Proprietary Information, which may be disclosed only as described elsewhere in this Article IX), (a) on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary, provided that such advisors are subject to confidentiality with regard to such information under an agreement or ethical obligation; (b) to a Third Party in connection with (i) a financing (or proposed financing) or an equity investment (or proposed investment) in such Party or its Affiliates, including to its shareholders and prospective shareholders, (ii) a merger, consolidation or similar transaction by such Party or its Affiliates, (iii) the sale of all or substantially all of the assets of such Party or its Affiliates, or (iv) in connection with a Securitization, provided that such Third Party executes a non-use and non-disclosure agreement and observes the same obligations of confidentiality as such Party owes under this Agreement with respect to Proprietary Information of the other Party; (c) to the United States Securities and Exchange Commission or any other securities exchange or governmental entity, including as required to make an initial or subsequent public offering, or (d) as otherwise required by law or regulation, provided that in the case of (c) and (d) the disclosing Party shall (x) if practicable, provide the other Party with reasonable advance notice of and an opportunity to comment on any such required disclosure, (y) if requested by such other Party, seek, or cooperate with such Party's efforts to obtain, confidential treatment or a protective order with respect to any such disclosure to the extent available at such other Party's expense, and (z) use good faith efforts to incorporate the comments of such other Party in any such disclosure or request for confidential treatment or protective order.

ARTICLE X - REPRESENTATIONS AND WARRANTIES

10.01 **Representations and Warranties of Each Party**. Each of Merck and Licensee hereby represents, warrants and covenants to the other Party hereto as follows:

(a) it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation;

(b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action;

(c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

(d) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions herein does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) a loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its corporate charter or other operative documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;

(e) except for the governmental and Marketing Authorizations required to market Licensed Product in the Territory, the execution, delivery and performance of this Agreement by such Party does not require the consent, approval or authorization of, or notice, declaration, filing or registration with, any governmental or Regulatory Authority and the execution, delivery or performance of this Agreement will not violate any law, rule or regulation applicable to such Party;

(f) this Agreement has been duly authorized, executed and delivered and constitutes such Party's legal, valid and binding obligation enforceable against it in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles; and

(g) it shall comply with all applicable material laws and regulations relating to its activities under this agreement.

10.02 Licensee's Representations. Licensee hereby represents, warrants and covenants to Merck as follows:

(a) during the Term of this Agreement it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the Act;

(b) its strategy incorporates the capacity and resources to Develop and Commercialize Licensed Product and to Manufacture Licensed Compound.

10.03 Merck's Representations. Merck hereby represents, warrants and covenants to Licensee as follows:

(a) Merck owns or has licensed with a sublicensable interest the Compound Patent Rights and the Merck Know-How and has the full legal right and power to grant to Licensee the licenses of the scope and on the terms granted herein;

(b) Merck has received no written communication claiming (or threatening to claim), and to the knowledge of Merck there is no pending claim, that the practice of the inventions described in the Compound Patent Rights infringes any patents or patent applications or other rights of any third party; and

(c) to its reasonable knowledge, as the Effective Date, the patents and patent applications listed in Schedule 1.8 are the only patents in force and pending patent applications owned or controlled by Merck (and/or its Affiliates) that claim Licensed Compound as a composition of matter and are necessary for the Development or Commercialization of Licensed Compound as contemplated in the Development Plan.

10.04 No Inconsistent Agreements. Neither Party has in effect, and after the Effective Date neither Party shall enter into, any oral or written agreement or arrangement that would be inconsistent with its obligations under this Agreement.

10.05 Representation by Legal Counsel. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting of this Agreement. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party that drafted such terms and provisions.

10.06 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE X, LICENSED COMPOUND, LICENSED PRODUCT, COMPOUND PATENT RIGHTS AND MERCK KNOW-HOW ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

10.07 No Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY HERETO MAKES ANY REPRESENTATION AND EXTENDS NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED. IN PARTICULAR, BUT WITHOUT LIMITATION, MERCK MAKES NO REPRESENTATION AND EXTENDS NO WARRANTY CONCERNING WHETHER THE DESIGNATED COMPOUND OR A DESIGNATED PRODUCT IS FIT FOR ANY PARTICULAR PURPOSE OR SAFE FOR HUMAN CONSUMPTION.

ARTICLE XI - INDEMNIFICATION AND LIMITATION ON LIABILITY

11.01 Indemnification by Licensee. Licensee shall indemnify, defend and hold harmless Merck and its Affiliates, and each of its and their respective employees, officers, directors and agents (each, a "Merck Indemnified Party") from and against any and all liability, loss, damage, cost, and expense (including reasonable attorneys' fees), subject to the limitations in Section 11.05 (collectively, a "Liability") that a Merck Indemnified Party may incur, suffer or be required to pay resulting from or arising out of (i) the development, Manufacture, promotion, distribution, use, marketing, sale or other disposition of Licensed Compound and/or Licensed Product by Licensee, its Affiliates or sublicensees, (ii) any breach by Licensee of any of its representations, warranties and covenants contained in Sections 10.01, 10.02, and 10.04 herein, and (iii) the negligence and/or willful misconduct of Licensee, its Affiliates or sublicensees. Notwithstanding the foregoing, Licensee shall have no obligation under this Agreement to indemnify, defend or hold harmless any Merck Indemnified Party with respect to any Liabilities that result from the gross negligence or willful misconduct of Merck, Merck Indemnified Party or any of their respective employees, officers, directors or agents or that result from Merck's breach of its obligations under this Agreement.

11.02 Indemnification by Merck. Merck shall indemnify, defend and hold harmless Licensee and its Affiliates, and each of its and their respective employees, officers, directors and agents (each, a "Licensee Indemnified Party") from and against any Liability that a Licensee Indemnified Party may incur, suffer or be required to pay resulting from or arising in connection with (i) any breach by Merck of any of its representations, warranties and covenants contained in Sections 10.01, 10.03 and 10.04 herein and (ii) the negligence and/or willful misconduct of Merck. Notwithstanding the foregoing, Merck shall have no obligation under this Agreement to indemnify, defend or hold harmless any Licensee Indemnified Party with respect to any Liabilities that result from the gross negligence or willful misconduct of Licensee, Licensee Indemnified Party or any of their respective employees, officers, directors or agents or that result from Licensee's breach of its obligations under this Agreement,.

11.03 Conditions to Indemnification. The obligations of the indemnifying Party under Sections 11.01 and 11.02 are conditioned upon the delivery of written notice to the indemnifying Party of any potential Liability promptly after the indemnified Party becomes aware of such potential Liability. The indemnifying Party shall have the right to assume the defense of any suit or claim related to the Liability if it has assumed responsibility for the suit or claim in writing; however, if in the reasonable judgment of the indemnified Party, such suit or claim involves an issue or matter that could have a materially adverse effect on the business operations or assets of the indemnified Party, the indemnified Party may retain control of the defense or settlement thereof by providing written notice of such effect to the indemnifying Party, but in no event shall such action or notice be construed as a waiver of any indemnification rights that the indemnified Party may have at law or in equity. If the indemnifying Party defends the suit or claim, the indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. The foregoing notwithstanding, the Parties acknowledge and agree that failure of the indemnified Party to promptly notify the indemnifying Party of a potential Liability shall not constitute a waiver of, or result in the loss of, such Party's right to indemnification under Section 11.01 or 11.02. as appropriate, except to the extent that the indemnifying Party's rights, and/or its ability to defend against such Liability, are materially prejudiced by such failure to notify.

11.04 Settlements. Neither Party may settle a claim or action related to a Liability without the consent of the other Party, and such consent shall not be unreasonably withheld, if such settlement would impose any monetary obligation on the other Party or require the other Party to submit to an injunction or otherwise limit the other Party's rights under this Agreement. Any payment made by a Party to settle any such claim or action shall be at its own cost and expense.

11.05 Limitation of Liability. With respect to any claim by one Party against the other arising out of the performance or failure of performance of the other Party under this Agreement, the Parties expressly agree that the liability of such Party to the other Party for such breach shall be limited under this Agreement or otherwise at law or equity to direct damages only and in no event shall a Party be liable for punitive, exemplary or consequential damages.

[***] Indicates that information has been omitted.

11.06 Insurance. At such time as Licensee or any of its sublicensee begins to sell or distribute Product(s), Licensee shall, at its own expense, procure and maintain policies of comprehensive general liability insurance (including without limitation product liability insurance) **[***]**. All such policies shall name Merck as an additional insured , and insurers will waive all rights of subrogation against Merck. Upon Merck's request, Licensee will promptly provide for itself and its sublicensees copies of certificates of insurance evidencing such coverages. Licensee shall notify Merck not less than thirty (30) days in advance of any material change or cancellation of any policy. Licensee shall continue to maintain such insurance in effect after the expiration or termination of this Agreement during any period in which Licensee or its sublicensee continues to make, have made, use, sell, offer to sell or import Product. If any insurance is on a claims made basis, Licensee will maintain such insurance for a period of not less than five (5) years after it has ceased all commercial sale, distribution or use of any Product.

ARTICLE XII - TERM AND TERMINATION

12.01 Term and Expiration. This Agreement shall be effective as of the Effective Date and unless terminated earlier by mutual written agreement of the Parties or pursuant to Sections 12.02 or 12.03 below, the term of this Agreement shall continue in effect on a country-by-country and product-by-product basis until the expiration of Licensee's obligation to pay royalties under Article VII herein (the "Term"). Upon expiration of this Agreement in its entirety, Licensee's license pursuant to Section 2.01 shall become a fully paid-up, perpetual non-exclusive license.

12.02 Termination by Licensee.

(a) Licensee's Right to Terminate. Licensee shall have the unilateral right to terminate this Agreement in its entirety without cause at any time by giving one hundred eighty (180) days advance written notice to Merck.

(b) Effect of Termination. Upon termination of this Agreement in its entirety under Section 12.02(a), the rights and obligations hereunder shall terminate except as provided under Section 12.04. and all rights to Licensed Compound and Licensed Product shall revert to Merck pursuant to Section 12.05.

12.03 Termination for Cause.

(a) Termination for Cause. This Agreement may be terminated, in its entirety by written notice by either Party at any time during the term of this Agreement:

(i) upon or after the breach of any material provision of this Agreement if the breaching Party has not cured such breach within sixty (60) days following receipt of written notice from the non-breaching Party requesting cure of the breach or, if such breach is not susceptible of cure within such sixty (60) day period , the breaching Party has not taken appropriate steps to commence such cure during such sixty (60)-day period and continued to diligently pursue such cure in a manner reasonably assuring such cure within a reasonable period of time thereafter (not to exceed one hundred eighty (180) days). Any right to terminate under this Section 12.03(a) shall be stayed and the cure period tolled in the event that, during any cure period, the Party alleged to have been in material breach shall have initiated dispute resolution in accordance with Article XIII with respect to the alleged breach, which stay and tolling shall last so long as the allegedly breaching Party diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings; or

[***] Indicates that information has been omitted.

(ii) upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings by or against the other Party, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party, or in the event a receiver or custodian is appointed for such Party's business, or if a substantial portion of such Party's business is subject to attachment or similar process; provided, however, that in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the proceeding is not dismissed within one hundred twenty (120) days after the filing thereof.

(b) Effect of Termination for Cause on License.

(i) Termination by Licensee for Cause. In the event this Agreement is properly terminated by Licensee under Section 12.03(a)(i), **[***]**. All other rights and obligations hereunder shall terminate except as provided under Section 12.04.

(ii) Termination by Merck for Cause. In the event this Agreement is terminated by Merck under Section 5.03, 8.07, 12.03(a) and/or 14.01(b) the rights and obligations hereunder shall terminate except as provided under Section 12.04, and all rights to Licensed Compound and Licensed Product shall revert to Merck pursuant to Section 12.05.

12.04 Effect of Termination Generally. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination, and the provisions of Article I (Definitions), Article IX (Confidentiality), Article XI (Indemnification and Limitation on Liability), Article XIII (Dispute Resolution), Article X1V (Miscellaneous) and Section 10.05, Section 10.06, Section 12.03(b), Section 12.04, Section 12.05 and Section 12.06 shall survive the expiration or termination of this Agreement. Any expiration or early termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to termination, including the obligation to pay royalties for Licensed Product sold prior to such termination.

12.05 Licensed Product Reversion. Upon termination of this Agreement in its entirety by Merck for any reason or by Licensee pursuant to Section 12.02, at Merck's option and upon Merck's written request, the following provisions shall apply:

(a) Effective upon such termination, without further action by either Party, Merck shall have a worldwide, fully paid-up, royalty-free, sublicensable, exclusive and perpetual license from Licensee under any Licensee Know-How or Licensee Patent Rights existing at the time of termination and that is necessary or useful for the use, Development, Manufacture, or Commercialization of Licensed Product that is then being Developed or Commercialized by Licensee. Merck's license under this Section 12.05(a) shall be limited solely to the right to Develop, make, have made, use, import, export, Commercialize, offer to sell and sell such Licensed Product in the Field and Territory.

(b) Licensee shall reasonably cooperate with Merck in order to enable Merck to assume responsibility for the Development, Manufacture and/or Commercialization of all Licensed Products then being Developed, Manufactured or Commercialized by Licensee. Such cooperation and assistance shall be provided in a timely manner, not to exceed six (6) months, and shall include without limitation:

(i) Licensee shall transfer to Merck (or its nominee) all INDs, Marketing Authorizations, drug approval applications for Marketing Authorizations, and all supporting documentation for such filings and applications, made or obtained by Licensee or its Affiliates or any of its sublicensees to the extent relating to Licensed Product then being Commercialized or in Development.

(ii) Licensee shall assign to Merck all of its rights in any trademarks and shall transfer to Merck all of its rights in any domain names containing trademarks, in each case to the extent that such trademarks have actually been or are planned to be utilized by Licensee in connection with the Commercialization of Licensed Product in the Field. Any assignment or transfer to Merck pursuant to this Section 12.05(b)(ii) shall be at no cost to Merck.

(iii) Licensee shall transfer to Merck (or its nominee), to the extent not previously provided, a copy of all Licensee Know-How in its possession or under its control relating to any Licensed Product then being Commercialized or in clinical Development by Licensee and reasonably necessary or useful for its continued Development, Manufacture and/or Commercialization, including without limitation all information contained in Licensee's regulatory and/or safety databases, all in the format then currently maintained by Licensee.

(iv) Upon the written request of Merck, Licensee shall use reasonable and diligent efforts to assign to Merck any sublicenses previously granted by Licensee related to Licensed Product.

(v) Upon the written request of Merck, Licensee, its Affiliates and its sublicensees shall complete any clinical studies related to Licensed Product in the Field that (x) are being conducted under Licensee's IND for Licensed Product and arc ongoing as of the date this Agreement is terminated, and (y) for which it is not practicable to transfer responsibility for conducting such studies to Merck; provided, however, that Merck agrees to reimburse Licensee for all Development costs incurred by Licensee after termination in completing such studies.

(vi) Upon the request of Merck, Licensee shall transfer to Merck, at a price to be agreed in good faith, that shall not be more than one hundred and twenty-five percent (125%) of Licensee's fully allocated Manufacturing cost for Licensed Product, all quantities of Licensed Product in the possession of Licensee or its Affiliates (including, without limitation, clinical trial supplies and Licensed Product intended for commercial sale).

(vii) At Merck's written request, Licensee shall promptly provide to Merck copies of all clinical trial, contract manufacturing, or service agreements entered into by Licensee or its Affiliates with respect to Licensed Product. At Merck's written request, Licensee shall promptly assign (or cause to be assigned), such agreements to Merck, to the extent such assignment is permitted under such agreement or, in the case that such agreements involve products other than Licensed Product, to the extent that the portion of the agreement involving solely Licensed Product can be assigned. In the event that such an assignment is not permitted under a particular clinical trial, contract manufacturing, or service agreement, then Licensee shall reasonably cooperate (at Merck's request) to assist Merck in obtaining the benefits of such agreement.

(viii) The Parties shall use diligent efforts to complete the transition of the Development, Manufacture and Commercialization of Licensed Product from Licensee to Merck pursuant to this Section 12.05 as soon as is reasonably possible.

(ix) Notwithstanding anything to the contrary in this Section 12.05, any termination of this Agreement by Merck pursuant to Section 12.03(a)(i) or Section 5.03 shall be stayed and the cure period tolled in the event that, during any cure period, Licensee shall have initiated dispute resolution in accordance with Article XIII with respect to the alleged breach, which stay and tolling shall last so long as Licensee diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings.

12.06 Return of Merck Know-How. Not later than thirty days (30) days after the termination of this Agreement in its entirety by Merck for any reason or by Licensee pursuant to Section 12.02, Licensee shall, at Merck's discretion, either destroy or return or cause to be returned to Merck, all Merck Know-How in tangible form received from Merck and any other documents containing Merck's Proprietary information, and all copies thereof, including those in the possession of the receiving Party's Agents pursuant to Section 9.01(b), except that Licensee may retain one (1) copy of Merck Proprietary Information in its confidential files in a secure location solely for the purposes of (i) determining its obligations hereunder, (ii) complying with any applicable regulatory requirements, or (iii) defending against any product liability claim.

ARTICLE XIII - DISPUTE RESOLUTION

13.01 Informal Discussions. Except as otherwise provided herein, in the event of any controversy or claim arising out of or relating to this Agreement, or the rights or obligations of the Parties hereunder, or the relationship between the Parties with respect to Licensed Compound or Licensed Product, the Parties shall first try to settle their differences amicably between themselves. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within thirty (30) days after such notice appropriate representatives of the Parties shall meet for attempted resolution by good faith negotiations. If such representatives are unable to resolve promptly such disputed matter within the said thirty (30) days, either Party may refer the matter by written notice to the other to the appropriate therapy area Vice President of Merck Research Laboratories, or his designee, and the Chief Executive Officer of Licensee, or his designee, for discussion and resolution. If such individuals or their designees are unable to resolve such dispute within thirty (30) days of such written notice, either Party may initiate arbitration proceedings in accordance with the provisions of this Article XIII.

13.02 Arbitration. All disputes arising out of or relating to this Agreement, or the rights or obligations of the Parties hereunder, or relating in any way to the relationship between the Parties with respect to Licensed Compound or Licensed Product, shall be finally and exclusively settled by arbitration by a panel of three (3) arbitrators, provided such dispute is not an "Excluded Claim". As used in this Section, the phrase "Excluded Claim" shall mean a dispute, controversy or claim that concerns (a) the validity or infringement of a patent, trademark or copyright; or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory

(a) The arbitration proceeding shall be conducted under the Commercial Arbitration Rules of the American Arbitration Association ("AAA") with such proceedings to be held in Newark, New Jersey, United States. In all cases, the arbitration proceedings shall be conducted in the English language, and all documents that are submitted in the proceeding shall be in the English language. Judgment upon the award rendered by arbitration may be issued and enforced by any court having competent jurisdiction.

(b) If a Party intends to begin an arbitration to resolve a dispute, such Party shall provide written notice to the other Party, informing the other Party of such intention and any statement of claim required under the applicable arbitration rules (as determined in accordance with Section 13.02(a)). Within twenty (20) business days after its receipt of such notice, the other Party shall, by written notice to the Party initiating arbitration, add any additional issues to be resolved that would be considered mandatory counterclaims under New Jersey law. For clarity, the resolution of any disputes regarding such counterclaims shall be conducted in the same proceedings as the initial claims.

(c) Within forty-five (45) days following the receipt of the notice of arbitration, the Party referring the matter to arbitration shall appoint an arbitrator and promptly notify the other Party of such appointment. The other Party shall, upon receiving such notice, appoint a second arbitrator within twenty one (21) days, and the two (2) arbitrators shall, within fifteen (15) days of the appointment of the second arbitrator, agree on the appointment of a third arbitrator who will act with them and be the chairperson of the arbitration panel. In the event that either Party shall fail to appoint an arbitrator within thirty (30) days after the commencement of the arbitration proceeding, the arbitrator shall be appointed by the AAA. In the event of the failure of the two (2) arbitrators to agree within sixty (60) days after the commencement of the arbitration proceeding to appoint the chairperson, the chairperson shall also be appointed by the AAA.

(i) All of the arbitrators shall have significant legal or business experience in pharmaceutical licensing matters. The arbitrators shall not be employees, directors or shareholders of either Party or any of their Affiliates.

(ii) Each Party shall have the right to be represented by counsel throughout the arbitration proceedings.

(iii) To the extent possible, the arbitration hearings and award will be maintained in confidence.

(iv) In any arbitration pursuant to this Agreement, the award or decision shall be rendered by a majority of the members of the panel provided for herein, with each member having one (1) vote. The arbitrators shall render a written decision with their resolution of the dispute that shall set forth in reasonable detail the facts of the dispute and the reasons for their decision. The decision of the arbitrators shall be final and non-appealable and binding on the Parties.

13.03 Injunctive Relief. By agreeing to arbitration, the Parties do not intend to deprive any competent court of such court's jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of the arbitration proceedings and the enforcement of any award or judgment. Without prejudice to such provisional remedies in aid of arbitration as may be available under the jurisdiction of a national court, the court of arbitration shall have full authority to grant provisional remedies and to award damages for failure of any Party to respect the court of arbitration's order to that effect.

13.04 Expenses of Arbitration and Expert Determination. Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; *provided*, *however*, that the arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges and travel expenses). Absent the filing of an application to correct or vacate the arbitration award as permitted by applicable law, each Party shall fully perform and satisfy the arbitration award within fifteen (15) days of the service of the award.

ARTICLE XIV - MISCELLANEOUS

14.01 Assignment/Change of Control.

(a) **Assignment**. Neither this Agreement nor any or all of the rights and obligations of a Party hereunder may be assigned, delegated, sold, transferred, sublicensed (except as otherwise provided herein) or otherwise disposed of, by operation of law or otherwise, to any Third Party without the prior written consent of the other Party, and any attempted assignment, delegation, sale, transfer, prohibited sublicense or other disposition, by operation of law or otherwise, of this Agreement or of any rights or obligations hereunder contrary to this Section 14.01 shall be a material breach of this Agreement by the attempting Party, and shall be void and without force or effect; provided, however, that either Party may, without such consent of such Party, assign the Agreement and its rights and obligations hereunder to an Affiliate or in connection with the transfer or sale of all or substantially all of its assets related to the division or the subject business, or in the event of its merger or consolidation or change in control or similar transaction. This Agreement shall be binding upon, and inure to the benefit of, each Party, its Affiliates, and its permitted successors and assigns. Each Party shall be responsible for the compliance by its Affiliates with the terms and conditions of this Agreement.

(b) Change of Control at Licensee. In the event that any Change of Control (as defined below) causes Licensee's rights and obligations hereunder to pass to any Third Party, such Third Party shall, within sixty (60) days after the effective date of such Change of Control, notify Merck of its intentions with regard to the Development and Commercialization of Licensed Product under this Agreement. If the Third Party succeeding to Licensee's rights and obligations under this Agreement decides it will not continue the Development and/or Commercialization of Licensed Product, then Merck shall have the right to terminate this Agreement upon thirty (30) days written notice to Licensee, without any opportunity to cure. If the Third Party succeeding to Licensee's rights and obligations under this Agreement decides to continue the Development and Commercialization of Licensed Product, then all of the rights and obligations of Licensee under this Agreement shall inure to such Third Party; provided, that within forty-five (45) days after the Change of Control, such Third Party successor shall submit to Merck a new Development Plan for the next succeeding twelve (12) month period. Merck shall have the right to comment on the new Development Plan in accordance with the procedures set forth in Section 3.02(b).

(c) Definition of Change of Control. As used in this Section 14.01 the term "Change of Control" shall mean (i) any merger, reorganization, consolidation or combination in which a Party to this Agreement is not the surviving corporation, or (ii) where any "person" (within the meaning of Sections 13(d) and 14 (d)(2) of the Securities Exchange Act of 1934), excluding Licensee and its Affiliates, is or becomes the beneficial owner, directly or indirectly, of securities of the Party representing 50% or more of either (a) the then-outstanding shares of common stock of the Party or its parent corporation, or (b) the combined voting power of the Party's then-outstanding voting securities; or (iii) if individuals who as of the Effective Date constitute the Board of Directors of the Party or its parent corporation (the "Incumbent Board") cease for any reason to constitute at least a majority of such Board of Directors; provided, however, that any individual becoming a director subsequent to the Effective Date whose election, or nomination for election by the Party's shareholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a person other than the Incumbent Board; or (iv) approval by the shareholders of a Party of a complete liquidation or the complete dissolution of such Party. For the avoidance of doubt, any debt or equity capital raising transaction or series of related debt or equity capital raising transactions entered into by Licensee for purposes of financing Licensee's ongoing operations or other use contemplated by its then-current business plan shall not constitute a Change of Control hereunder.

14.02 Governing Law. This Agreement shall be governed, interpreted and construed in accordance with the laws of the State of New Jersey, without giving effect to its conflict of law principles. Subject to the terms of this Agreement, all disputes under this Agreement shall be governed by binding arbitration pursuant to the mechanism set forth in Article XIII herein.

14.03 Waiver. Any delay or failure in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, nor operate to bar the exercise or enforcement thereof at any time or times thereafter, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

14.04 Independent Relationship. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

14.05 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America that may be imposed upon or related to Merck or Licensee from time to time by the government of the United States of America. Furthermore, Licensee agrees that it will not export, directly or indirectly, any technical information acquired from Merck under this Agreement or any products using such technical information to any country for which the United States government or any agency thereof at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the Department of Commerce or other agency of the United States government when required by an applicable statute or regulation.

14.06 Entire Agreement; Amendment. This Agreement, including the Exhibits and Schedules hereto and thereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties with regard to the subject matter of this Agreement in the Territory. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change, waiver or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

14.07 Notices. Any notice required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile or electronic mail (and promptly confirmed by the other Party), sent by nationally-recognized overnight courier or sent by registered or certified mail; postage prepaid, return receipt requested, addressed as follows.

if to Licensee, to:	Ammonett Pharma LLC 3606 Salles Ridge Court Midlothian, VA, 23113 Attention: Kevin P Tully CGA E Mail: kptully@hotmail.com
if to Merck, to:	Merck Sharp & Dohme Corp. One Merck Drive P.O. Box 100, WS3AB-05 Whitehouse Station, NJ 08889-0100 Attention: Office of Secretary Facsimile No.: (908)735-1246
and	Merck Sharp & Dohme Corp. 2000 Galloping Hill Rd Mail Code 4385 Kenilworth, NJ 07033 Attention: Head of Global Outlicensing Facsimile: (908) 740-4040

Any such notice shall be deemed to have been received on the earlier of the date actually received or the date five (5) days after the same was posted or sent. Either Party may change its address or its facsimile number by giving the other Party written notice, delivered in accordance with this Section 14.07.

14.08 Force Majeure. Failure of any Party to perform its obligations under this Agreement (except the obligation to make payments when properly due) shall not subject such Party to any liability or place them in breach of any term or condition of this Agreement to the other Party if such failure is due to any cause beyond the reasonable control of such non-performing Party ("Force Majeure"), unless conclusive evidence to the contrary is provided. Causes of non-performance constituting Force Majeure shall include, without limitation, acts of God, fire, explosion, flood, drought, war, riot, sabotage, embargo, strikes or other labor trouble, failure in whole or in part of suppliers to deliver on schedule materials, equipment or machinery, interruption of or delay in transportation, a national health emergency or compliance with any order or regulation of any government entity acting with color of right. The Party affected shall promptly notify the other Party of the condition constituting Force Majeure as defined herein and shall exert reasonable efforts to eliminate, cure and overcome any such causes and to resume performance of its obligations with all possible speed; provided that nothing herein shall obligate a Party to settle on terms unsatisfactory to such Party any strike, lockout or other labor difficulty, any investigation or other proceeding by any public authority or any litigation by any Third Party. If a condition constituting Force Majeure as defined herein exists for more than ninety (90) consecutive days, the Parties shall meet to negotiate a mutually satisfactory resolution to the problem, if practicable. If the Parties cannot in good faith reach a satisfactory resolution to the problem within sixty (60) days of meeting, the matter shall be handled pursuant to the dispute resolution provisions of Article XIII herein.

14.09 Severability. If any provision of this Agreement is declared illegal, invalid or unenforceable by a court having competent jurisdiction, it is mutually agreed that this Agreement shall continue in accordance with its terms except for the part declared invalid or unenforceable by order of such court, provided, however, that in the event that the terms and conditions of this Agreement arc materially altered, the Parties will, in good faith, renegotiate the terms and conditions of this Agreement to reasonably substitute such invalid or unenforceable provisions in light of the intent of this Agreement.

14.10 Extension to Affiliates. Merck shall have the right to extend the rights, licenses, immunities and obligations under this Agreement to one or more Affiliates. All applicable terms and provisions of this Agreement shall apply to such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to Merck.

14.11 Counterpart. This Agreement shall become binding when any one or more counterparts of it, individually or taken together, shall bear the signatures of each of the Parties hereto. This Agreement may be executed in any number of counterparts, each of which shall be an original as against either Party whose signature appears thereon, but all of which taken together shall constitute but one and the same instrument.

14.12 Captions. The captions of this Agreement are solely for the convenience of reference and shall not affect its interpretation.

14.13 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

14.14 **Signatures**. For purposes of this Agreement, signatures sent by facsimile or PDF shall also constitute originals.

IN WITNESS WHEREOF, this Agreement has been executed by the duly authorized representatives of the Parties.

MERCK SHARP & DOHME CORP.

By: /s/ Iain Dukes

Title: Senior Vice President Licensing & External Scientific Affairs

Date: 22 Oct. 2013

AMMONETT PHARMA LLC

By: /s/ Kevin P Tully

Title: Chief Executive Officer

Date: 23rd October 2013

Exhibit 10.7

Certain identified information in this document has been excluded because it is both (i) not material and (ii) would likely cause competitive harm if publicly disclosed. [***] indicates where such information has been omitted.

ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (this "Agreement") is made as of the 26th day of July, 2018 by and among Lumos Pharma, Inc., a Delaware corporation ("Purchaser"), and Ammonett Pharma LLC, a Delaware limited liability company ("Seller" or the "Company"), and each of the Key Individuals.

RECITALS

A. Seller owns, holds, and/or has rights to certain assets relating to a product known as Oratrope™ (the "Product"), which Seller is developing for the treatment of growth hormone deficiency.

B. Purchaser desires to purchase, and Seller desires to sell, substantially all of the assets of Seller relating to the Product, on the terms and subject to the conditions contained in this Agreement.

C. Purchaser desires to assume, and Seller desires to assign, certain liabilities of Seller relating to the Product, on the terms and subject to the conditions contained in this Agreement.

D. To induce Purchaser to enter into this Agreement, (i) each of the Key Individuals (as defined below) has entered into a consulting agreement with Purchaser or any of its Affiliates, and (ii) each of the Persons listed on Exhibit A hereto (each, a "Member" and collectively, the "Members") has agreed to make the representations and warranties and be bound by the other obligations set forth in an acknowledgement, waiver and release in the form attached as Exhibit D hereto.

E. Capitalized terms used and not defined in this Agreement shall have the meaning ascribed to them on Annex I hereto.

AGREEMENT

NOW, THEREFORE, for and in consideration of the mutual covenants, agreements, representations and warranties contained in this Agreement and for other good and valuable consideration, the parties agree as follows:

ARTICLE 1. PURCHASE OF ASSETS; ASSUMPTION OF SELECT LIABILITIES

1.1 Assets. Seller hereby sells, assigns, transfers, conveys and delivers to Purchaser, and Purchaser hereby purchases, acquires and accepts from Seller, all of Seller's right, title, and interest in, to and under all of the assets, properties and rights of every kind and nature (other than the Excluded Assets, as defined below) that relate to, are used or held for use in connection with the research, development, registration, commercialization, or any other use or exploitation of the Product, including under the Merck License Agreement (the "Business") (except those assets that are defined in Section 1.2 as Excluded Assets). All of the Assets sold and purchased hereunder are collectively referred to as the "Assets" and individually referred to as an "Asset." The Assets include, without limitation, all of the following:

(a) all raw materials or ingredients for, components of, works in progress of, firm orders for, inventory in transit of, and inventory of Product or the Business, including clinical supply, whether held by Seller, Merck or any Person on behalf of Seller (collectively, "Inventory");

(b) all Intellectual Property that is related to the Product or the Business (the "Intellectual Property Assets"), including any patents and patent applications licensed to Seller under any Assigned Contracts as set forth on Schedule 1.1(b)(1) (the "Seller-Licensed Intellectual Property Assets") and any patents and patent applications owned by Seller as set forth on Schedule 1.1(b)(2) (the "Seller-Owned Intellectual Property Assets");

(c) all goodwill of the Seller associated with the Business;

(d) all Contracts set forth on Schedule 1.1(d) (the "Assigned Contracts");

(e) all rights, remedies, defenses, claims, rights to offset, and causes of action against customers, suppliers, insurers or any other Person, whether known or unknown, relating to or arising from the Business, Assets or any Assumed Liability (as defined below), whether arising before, on or after the Closing Date, and all rights to enforce any assignment of, license to, or confidentiality covenant with respect to, any Intellectual Property Asset;

(f) all books and records of Seller that directly relate to the Business, including all clinical and preclinical reports, laboratory notebooks, copies of all supplier lists, marketing studies, consultant reports, physician databases, and correspondence with respect to the Product to the extent maintained by Sellers, all reports to and correspondence with any Regulatory Authority, exception reports and investigations, specifications for raw materials and Regulatory Authority communication thereon, including communication relating to manufacturing or packaging with any of Regulatory Authority (as defined in Section 4.13(a)), vendors, or suppliers and all complaint files and adverse event files with respect to the Product; and

(g) all permits, authorizations, approvals, clearances, registrations, certificates, or similar rights obtained or required to be obtained from any Governmental Entity in connection with the operation of the Business, including (i) approvals, clearances or registrations which have been received by the Sellers and their Affiliates, for the investigation, clinical testing, sale, distribution and/or marketing of Product, and any applications therefor (including any NDAs and INDs and including all Orphan Drug Designations) and (ii) all dossiers, reports, data and other written materials filed as part of such approvals, registrations, or applications, or maintained by the Sellers and their Affiliates and relating to such approvals or registrations ((i) and (ii) together, the "Product Registrations").

Seller has made a good faith attempt to list all of the Assets in the schedules provide in Section 1.1; provided, however, notwithstanding the foregoing, any failure to list an Asset thereon shall not mean that such item is not an Asset purchased by Purchaser hereunder. At the Closing, the Assets shall be directly conveyed, transferred, assigned and delivered by Seller to Purchaser, free and clear of all Encumbrances.

1.2 Excluded Assets. Notwithstanding anything to the contrary herein, the Assets purchased hereunder shall not include, and Seller will retain all of its existing right, title and interest in and to, and there will be excluded from the sale, conveyance, transfer, assignment and delivery, (i) those assets set forth on Schedule 1.2, and (ii) all cash, accounts receivable, Tax Returns and related workpapers, and Tax refunds attributable to the Assets or the Business for all taxable periods (or portions thereof) ending on or prior to the Closing Date (collectively, the "Excluded Assets"), which Excluded Assets shall remain the property of Seller after Closing.

1.3 Assumed Liabilities. Purchaser hereby assumes, and Seller hereby assigns to Purchaser, Seller's obligations under the Assigned Contracts, but only to the extent that such obligations thereunder are required to be performed after the Closing Date and do not result from any failure to perform, improper performance, warranty or other breach, default or violation by Seller (the "Assumed Liabilities").

1.4 Retained Liabilities. Other than the Assumed Liabilities, Purchaser shall not assume and shall not be liable for, and Seller shall retain and, as between Purchaser and Seller, remain solely liable for and obligated to discharge, all liabilities and obligations of Seller, whether known or unknown, accrued or not accrued, fixed or contingent, and arising out of or resulting from the operation of the Business (each a "Retained Liability" and collectively, the "Retained Liabilities"), including but not limited to: (a) costs and expenses of Seller incurred or to be incurred by it in the negotiation and preparation of this Agreement and carrying out the transactions contemplated by this Agreement, including legal fees, (b) obligations, commitments or other liabilities of Seller (each a "Liability") under any Contract of Seller other than the Assigned Contracts, (c) Liabilities relating to the operation of the Business on or before the Closing, (d) Liabilities arising out of or relating to any product liability, breach of warranty or similar claim for injury to person or property which resulted from the use or misuse of, or otherwise related to Product, used, manufactured, or sold before the Closing, (e) Seller's liabilities for Taxes and all liabilities for Taxes attributable to the Assets or the Business for all taxable periods (or portions thereof) ending on or prior to the Closing Date, (f) litigation currently pending against Seller or, to the knowledge of Seller, currently threatened against Seller, (g) obligations, liabilities and commitments of Seller with respect to any employee or contractor of Seller or the Business, including for salary, wages, overtime, severance, benefits or other monetary obligations relating or owed to any of such employees or contractors, (h) obligations, commitments and liabilities arising from the Excluded Assets, and (i) other obligations, liabilities and commitments of Seller that are not an Assumed Liability.

1.5 Consent of Third Parties. Neither this Agreement nor the consummation of the transactions contemplated hereby shall be construed as an attempt or agreement to transfer or assign any Asset, the transfer or assignment of which would result in a violation of any applicable law or Contract if the consent of a third party is not obtained before such transfer or assignment ("Non-Assignable Assets") unless and until such consent shall have been obtained. Seller shall use its commercially reasonable efforts, with which Purchaser shall cooperate, in endeavoring to obtain such consents. Until such consent is obtained, Seller shall cooperate with Purchaser in any lawful arrangement designed to provide Purchaser with the benefits of such Non-Assignable Assets at no cost to Purchaser in excess of the cost Purchaser would have incurred (without modification to the terms of any Contract that is an Non-Assignable Asset) if the consent had been obtained.

ARTICLE 2. PURCHASE, PAYMENT AND TAXES

2.1 Purchase Price. In consideration for the sale, transfer and assignment by Seller of the Assets and in consideration of the representations, warranties, covenants and indemnities of Seller set forth herein, Purchaser hereby agrees to deliver and pay to Seller or on Seller's behalf an amount equal to:

(a) at Closing (as defined below) in accordance with the Funds Flow Memorandum (as defined below), a cash amount equal to $3,500,000 (the "Closing Payment"), minus amounts equal to,

(i) any Indebtedness of Seller or the Business that remains outstanding as of the Closing Date and is identified on Schedule 2.1(a)(i), which such Indebtedness shall be paid to the applicable creditor as set forth in the Funds Flow Memorandum; and

(ii) any Transaction Expenses that remain outstanding as of the Closing Date, which such Transaction Expenses shall be identified on Schedule 2.1(a)(ii) and shall be paid to the applicable recipient as set forth in the Funds Flow Memorandum; plus

(b) additional amounts up to and subject to the terms and conditions set forth on Exhibit B hereto (the "Subsequent Payments, the Subsequent Payments together with the Closing Payment, the "Total Purchase Price").

2.2 Purchase Price Allocation. Purchaser shall provide to the Seller for its review and approval a schedule, which schedule shall be periodically updated as additional payments are made pursuant to Section 2.1(b) of this Agreement, which schedule shall allocate the sum of the purchase price for the Assets, the Assumed Liabilities and any other relevant items among the Assets for all purposes (including Tax and financial accounting purposes) in a manner consistent with the Assets' respective fair market values (the "Allocation Schedule"). Purchaser and Seller will use reasonable efforts to agree to the contents of each Allocation Schedule and upon such agreement shall be bound by the Allocation Schedule and act in accordance with the Allocation Schedule in all federal, state and local Tax Returns (including, without limitation, Form 8883).

2.3 Taxes. All transfer, documentary, sales, use, value added, duties, stamp and registration Taxes and all conveyance fees, recording charges and other fees and charges (including any penalties and interest) incurred in connection with the consummation of the transactions contemplated by this Agreement, shall be borne half by Seller and half by Purchaser. Purchaser and Seller agree, upon request, to use their respective reasonable best efforts to obtain any certificate or other document from any tax authority or any other Person as may be necessary to mitigate, reduce or eliminate any Tax that could be imposed (including with respect to the transactions contemplated hereby.

ARTICLE 3. MUTUAL REPRESENTATIONS AND WARRANTIES

Each party hereby represents and warrants to the other party that the following representations and warranties as to such party are true, accurate and complete as of the date hereof:

3.1 Organization and Good Standing. Purchaser is a corporation duly incorporated and validly existing under the laws of the State of Delaware and Seller is a limited liability company duly organized and validly existing under the laws of the State of Delaware. Each party has all requisite power and authority to execute and deliver and perform its obligations under this Agreement.

3.2 Authorization. The execution and delivery of this Agreement and performance by each party of its obligations hereunder, and all transactions contemplated hereby, have been duly and validly authorized by all necessary action on the part of such party. This Agreement has been, and the other agreements and documents required to be delivered by each party in accordance with the provisions hereof will be, duly executed and delivered on behalf of each party; and this Agreement constitutes, and such agreements and documents when executed and delivered will constitute, the valid and binding obligations of such party, enforceable in accordance with their respective terms, except as enforcement may be limited by applicable bankruptcy, insolvency, reorganization or similar laws from time to time in effect affecting creditor's rights generally and by legal and equitable limitations on the availability of specific remedies.

3.3 Conflicts with Other Agreements; Consents. The execution and delivery by the parties of this Agreement and the performance by such party of its obligations hereunder will not conflict with or result in a breach of or constitute a default under any contract, license, indenture, loan agreement, restriction, lien, Encumbrance or other obligation or liability to which such party is or by which such party is affected or bound; nor is the effectiveness or enforceability of this Agreement or such other documents adversely affected by any provision of the organizational documents of Seller or Purchaser, as applicable. No consent, approval or agreement of any person, party, court, government or entity is required to be obtained by either party hereto in connection with the execution, delivery or performance of this Agreement.

3.4 Brokers and Finders. There is no investment banker, broker, finder, financial advisor or other financial intermediary that has been retained by or is authorized to act on behalf of such party or any of its Affiliates that is entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

ARTICLE 4. REPRESENTATIONS AND WARRANTIES OF SELLER AND KEY INDIVIDUALS

Subject to such exceptions as are disclosed in the disclosure schedule dated as of the date hereof and delivered herewith by Seller to Purchaser (the "Disclosure Schedule") corresponding to the applicable section and subsection or clause of this Article 4 (the "Applicable Article 4 Provision") (or disclosed in any other section, subsection or clause of the Disclosure Schedule; provided that it is reasonably apparent on its face, upon a reading of the disclosure without any independent knowledge on the part of the reader regarding the matter disclosed, that such disclosure is responsive to the Applicable Article 4 Provision), Seller and, solely for the purposes of Section 4.3 and Section 4.6(c), each Key Individual, hereby jointly and severally represent and warrant to Purchaser that the following representations and warranties are true, accurate and complete as of the date hereof:

4.1 Title to Assets; Subsidiaries.

(a) Seller has good and marketable title to all the Assets (other than the Assigned Contracts and the Seller-Licensed Intellectual Property Assets), free and clear of Encumbrances, other than Permitted Encumbrances. Seller is not a party to, and the Assets are not subject to, any judgment, judicial order, writ, injunction or decree that affects the Assets or the use thereof by Seller, Purchaser or any of its Affiliates.

(b) Section 4.1(b) of the Disclosure Schedule sets forth a complete and correct list of any Seller's Affiliates (the "Seller Affiliates"). Seller does not own, directly or indirectly, any shares of capital stock or equity interests in any Person.

4.2 Sufficiency. The Assets are sufficient, are in satisfactory condition and constitute all assets necessary to operate the Business in substantially the same manner as previously and currently conducted by Seller.

4.3 Contracts. Set forth on Section 4.3 of the Disclosure Schedule is a true, accurate and complete list, and Seller has delivered or made available to Purchaser true, accurate and complete copies, of each Assigned Contract, including the Merck License Agreement, to which Seller is a party to or bound by and any amendment, supplement and modification (whether oral or written) in respect of thereto. There are no Contracts relating to the Business other than as disclosed to Purchaser and as set forth on Section 4.3 of the Disclosure Schedule. Each Assigned Contract is in full force and effect and is valid and enforceable in accordance with its terms. Seller is, and at all times has been, in compliance with all applicable terms and requirements of the Merck License Agreement. Seller is, and at all times has been, in compliance in all material respects with all applicable terms and requirements of each other Assigned Contract. Each other Person that has or had any obligation or liability under the Merck License Agreement is, and at all times has been, in compliance with all applicable terms and requirements of the Merck License Agreement. Each other Person that has or had any obligation or liability under any other Assigned Contract is, and at all times has been, in compliance in all material respects with all applicable terms and requirements of such Assigned Contract. No event has occurred or circumstance exists that (with or without notice or lapse of time) may contravene, conflict with or result in a breach of, or give Seller or other person the right to declare a default or exercise any remedy under, or to accelerate the maturity or performance of, or payment under, or to cancel, terminate or modify, any Assigned Contract. No event has occurred or circumstance exists under or by virtue of any Assigned Contract that (with or without notice or lapse of time) would cause the creation of any Encumbrance affecting any of the Assets. Seller has not given to or received from any other Person, at any time, any notice or other communication (whether oral or written) regarding any actual, alleged, possible or potential violation or breach of, or default under, any Assigned Contract. There are no renegotiations of, attempts to renegotiate or outstanding rights to renegotiate any material amounts paid or payable to Seller under current or completed Assigned Contracts and no such person has made written demand for such renegotiation. Except with respect to the noncompetition provisions set forth herein, Seller is not a party to any noncompetition or nonsolicitation agreement with any other party.

4.4 Intellectual Property; Technology, Preservation of Confidential Information.

(a) The Seller is the sole legal and beneficial owner of the Seller-Owned Intellectual Property Assets, free and clear of any Encumbrances. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of, or otherwise adversely affect, any ownership rights of Purchaser in the Seller-Owned Intellectual Property Assets or any right of Purchaser to exploit the Seller-Owned Intellectual Property Assets. The Seller has the sole right to file, prosecute and maintain all applications and registrations with respect to the Seller-Owned Intellectual Property Assets. Seller has not conducted its Business or used or enforced (or failed to use or enforce) the Intellectual Property Assets in a manner that would reasonably be expected to result in the abandonment, cancellation or unenforceability of any of the Intellectual Property Assets, and Seller has not taken (or failed to take) any action that would reasonably be expected to result in the forfeiture or relinquishment of any of the Intellectual Property Assets. Seller has not granted any license of or right to use, or authorized the retention of any rights in or joint ownership of, any Intellectual Property Assets. Seller has not transferred, sold, assigned, exclusively licensed, dedicated to the public, licensed pursuant to an open source license or covenanted not to exercise rights under any Intellectual Property developed by or on behalf of the Seller or previously owned or claimed to be owned by the Seller, which was used in the Business.

(b) Section 4.4(b)(1) of the Disclosure Schedule contains a true, complete and accurate list of the following types of Intellectual Property Assets owned by Seller, both domestic and foreign, along with the jurisdiction in which each such item of Intellectual Property has been registered or filed and the applicable registration, application or serial number or similar identifier: all patents and pending patent applications, all trademark registrations and pending trademark registration applications; all copyright registrations and pending copyright registration applications; and all domain name registrations and pending domain name registrations ("Seller-Owned Registered Intellectual Property Assets"). All of the Seller-Owned Registered Intellectual Property Assets are solely and exclusively owned by the Seller. Except as set forth on Schedule 4.4(b)(1), Seller is not aware of any issues relating to the validity of and/or the enforceability of the Seller-Owned Registered Intellectual Property Assets. Seller has taken all actions required to maintain the effectiveness of the Seller-Owned Registered Intellectual Property Assets. Seller has not received any notice of any pending or threatened action before any Governmental Entity challenging the use, ownership, or the validity, enforceability or registerability of any of the Seller-Owned Registered Intellectual Property Assets and Seller is not aware of any reasonable basis for any such challenge.

Section 4.4(b)(2) of the Disclosure Schedule contains a true, complete and accurate list of the following types of Intellectual Property Assets licensed to Seller in the Assigned Contracts, both domestic and foreign, along with the jurisdiction in which each such item of Intellectual Property has been registered or filed and the applicable registration, application or serial number or similar identifier: all patents and pending patent applications, all trademark registrations and pending trademark registration applications; all copyright registrations and pending copyright registration applications; and all domain name registrations and pending domain name registrations ("Seller-Licensed Registered Intellectual Property Assets"). Seller has not received any notice of any pending or threatened action before any Governmental Entity challenging the use, ownership, or the validity, enforceability or registerability of any of the Seller-Licensed Registered Intellectual Property Assets and Seller is not aware of any reasonable basis for any such challenge.

(c) Section 4.4(c) of the Disclosure Schedule contains a true, complete and accurate list of all unregistered trademarks, service marks, trade names, logos owned or used by Seller in the operation of the Business ("Unregistered Marks"). Seller has all necessary rights in the Unregistered Marks and there are no circumstances which might prevent Purchaser from continuing to use such Unregistered Marks. No Unregistered Marks or Seller-Owned Registered Intellectual Property Assets is alleged to be confusingly similar, to any trademark, logo, service mark, domain name or trade name owned, used or applied for by any third party in any jurisdiction in which the Seller uses such Unregistered Marks or Seller-Owned Registered Intellectual Property Assets.

(d) Section 4.4(d) of the Disclosure Schedule contains a true, complete and accurate list of all licenses, sublicenses and other agreements by or through which other Persons, including Seller's Affiliates, that grant Seller exclusive or non-exclusive rights or interests in or to any Intellectual Property that is used in or necessary for the conduct of the Business as currently conducted ("Seller In-Licenses"). Sellers have provided Purchaser with true and complete copies of all such Seller In-Licenses. All such Seller In-Licenses are valid, binding and enforceable between Seller and the other parties thereto, and Seller and such other parties are in full compliance with the terms and conditions of such Seller In-Licenses.

(e) Section 4.4(e) of the Disclosure Schedule contains a true, complete and accurate list of licenses, sublicenses and other agreements pursuant to which Seller grants rights or authority to any Person with respect to any Intellectual Property or Seller In-Licenses. Seller has provided Purchaser with true and complete copies of all such agreements. All such agreements are valid, binding and enforceable between Seller and the other parties thereto, and Seller and such other parties are in full compliance with the terms and conditions of such agreements.

(f) The Seller-Owned Intellectual Property Assets conveyed to Purchaser pursuant to this Agreement and the Intellectual Property expressly licensed in valid Assigned Contracts assigned to Purchaser pursuant to this Agreement, constitute all the Intellectual Property used in or held for use in the Business and all the Intellectual Property necessary to the conduct the Business. All Seller-Owned Intellectual Property Assets, and all Intellectual Property rights licensed pursuant to the Assigned Contracts, will be fully and validly transferred to Purchaser as part of the Assets. After Closing, all Seller-Owned Intellectual Property Assets will be fully transferable and assignable by Purchaser, in each case without restriction and without payment of any kind to any third party. Any Intellectual Property rights licensed to Seller and transferred to Purchaser as part of the Assets are not subject to any restrictions except as set forth in Seller In-Licenses identified on Section 4.4(d) of the Disclosure Schedule.

(g) Neither the conduct of the Business as currently or formerly conducted nor the use of the Product or Assets (a) to the Knowledge of the Seller, infringes or misappropriates (or will infringe or misappropriate) any patent, copyright, trademark, trade secret or any other intellectual property of a third party, (b) to the Knowledge of the Seller, violates any right to privacy or publicity of any Person, or (c) to the Knowledge of the Seller, constitutes unfair competition or unfair trade practices under the laws of any jurisdiction where the Business is currently conducted. Seller has no knowledge of any claims of such infringement, violation or unfair competition or unfair trade practices. To the Seller's knowledge, no Person is misappropriating, infringing, diluting (with respect to trademarks) or violating any Intellectual Property Assets.

(h) Seller has not disclosed any proprietary information embodying or related to the Assets including the Intellectual Property Assets other than to employees, consultants, professional advisors, licensees or distributors of Seller, and in each case, such disclosure has been pursuant to written agreements requiring the recipients to maintain the confidentiality of such information and appropriately restricting the use thereof. To the Seller's knowledge (i) there has been no misappropriation of any Intellectual Property Assets by any Person, (ii) no employee, independent contractor or agent of Seller has misappropriated any trade secrets or proprietary information of any other person or party in the course of performance as an employee, independent contractor or agent of the Seller, and (iii) no employee, independent contractor or agent of Seller is in default or breach of any term of any employment agreement, non-disclosure agreement, assignment of invention agreement or similar contract relating in any way to, or otherwise affecting, the Intellectual Property Assets or the Business.

(i) All current and former employees, officers, directors, consultants and contractors of the Seller who contribute or have contributed to the creation or development of any Intellectual Property Asset, or any other Intellectual Property used or held for use in the operation of the Business, have executed written instruments with the Seller assigning all rights, title and interest in and to any such contributions to the Seller. No current or former employee, officer, director, consultant or independent contractor has any right, moral right, claim, right to receive payment or remuneration, or interest in or with respect to any such contributions, any Intellectual Property Asset.

(j) Since January 1, 2015 Seller has, in all material respects (i) complied at all times with all applicable privacy laws and regulations and contractual obligations regarding the collection, processing, disclosure and use of all data consisting of personally identifiable information that is, or is capable of being, associated with specific individuals; (ii) complied with Seller's privacy policy substantially in the form provided to Purchaser or its counsel with respect to personally identifiable information; and (iii) taken all appropriate and industry standard measures to secure, protect and maintain the confidential nature of any personally identifiable information that Seller has collected or otherwise acquired.

4.5 Inventory. The items of Inventory of Seller are suitable, usable, and not expired, materially conform to generally accepted standards in the industry of which Seller is a part (including GMP), materially meet Seller's current standards and specifications, and comply in all material respects with applicable laws.

4.6 Employees.

(a) Other than the Key Individuals, Seller does not employs or engages, nor in the past two-years has employed or engaged, any employee, consultant or contractor in connection with the operation of the Business Seller now and during the two-year period immediately preceding the date of this Agreement has been in compliance, in all material respects, with all applicable laws respecting employment, employment practices, labor, terms and conditions of employment, occupational health and safety, layoffs, plant closings or reductions in force, employee classification and wages and, including all contractual commitments and all such laws relating to wages, hours, collective bargaining, discrimination, civil rights, safety and health, and workers' compensation.

(b) Seller has delivered or made available to Purchaser a true, complete and accurate list of all employees as of the date hereof and, to the extent such information may be shared consistent with applicable law, their names, titles, and current wages (salaries or hourly rates of pay), guaranteed bonuses and status as exempt or non-exempt. Seller has delivered or made available to Purchaser a true, complete and accurate list of all independent contractors or consultants who are natural persons and have performed services for Seller or the Business in any given calendar year during the last three calendar years and for who, to the knowledge of Seller, Seller is the primary service recipient. All Seller employees are at-will and each of them may terminate or be terminated from employment at any time with or without prior notice. All Seller employees are subject to written employment agreements or written offer letters, which have been delivered or made available to Purchaser.

(c) Other than compensation and benefits due and payable in the ordinary course of business and consistent with past practices, Seller has paid all (and there are no outstanding) wages, salaries, bonuses, commissions, wage premiums and other compensation that has become due and payable to their employees (including the Key Individuals) or other service providers pursuant to applicable law or Contract.

(d) During the two-year period immediately preceding the date of this Agreement, Seller has conducted background checks of its employees or employee of the Business when required by applicable Assigned Contracts, including obtaining all required consent forms. Seller's use of information obtained from such background checks had been compliant in all material respects with all applicable law and background check reports and verifications have been maintained consistent in all material respects with all applicable law, including applicable privacy and data security laws.

4.7 Litigation. Except as set forth in Section 4.7 of the Disclosure Schedule, there is no, and at no time in the two-year period immediately preceding the date of this Agreement has been, (a) any Proceeding or investigation pending or, to the knowledge of Seller, threatened, against Seller or the Members with respect to the Assets, any intellectual property rights therein and thereto or the Business, (b) existing or threatened product liability, warranty or other similar claims related to the Business, or any facts upon which a material claim of such nature could be based, against Seller or the Members for products or services which are defective or fail to meet any product or service warranties.

4.8 Taxes.

(a) Seller is, and has been treated as, a partnership for United States federal income Tax purposes and state income Tax purposes at all times from the date on which Seller was organized. Seller has filed or caused to be filed all Tax Returns required to be filed by Seller under applicable laws, and such Tax Returns are true and correct in all respects. Seller has made delivered or made available to Purchaser correct and complete copies of Seller's United States federal and state income and franchise Tax Returns which have been filed since 2014. Seller's Tax Returns have not been audited by any taxing authority. The Company has not received written notice from any tax authority that the Company has not filed a Tax Return required to be filed, or that the Company has not paid Taxes required to be paid, by the Company.

(b) Seller has, within the time and in the manner prescribed by law, paid all Taxes that were due and payable by Seller (whether or not shown on any Tax Return).

(c) None of the Assets is a Tax Sharing Agreement, and none of the Assumed Liabilities includes any liability under a Tax Sharing Agreement or any obligation to pay any Tax obligations of, or with respect to any transaction relating to, any other Person or indemnify any other Person with respect to any Tax.

(d) There is no currently effective agreement, waiver or consent providing for an extension of time with respect to the assessment of any Taxes or the filing of any Tax Returns.

(e) There are no (i) currently effective powers of attorney granted by Seller concerning any Tax matter, (ii) agreements entered into by Seller with any taxing authority that would have a continuing effect on the Assets or the Business after the Closing or (iii) Encumbrances (and immediately following the Closing there will be no Encumbrances) on the Assets relating to or attributable to Taxes other than Encumbrances for Taxes not yet due and payable.

(f) There is no Proceeding, investigation, examination, audit, demand, notice of deficiency or assessment against Seller pending (or any threat of any of the foregoing that has been communicated to Seller) with respect to any Tax and no notice of such an audit or examination has been received by Seller and no written claim has ever been made by any taxing authority where Seller does not file Tax Returns that it may be subject to taxation in that jurisdiction.

(g) All Taxes required by applicable law to be withheld by Seller on or before the Closing have been or will be withheld and paid when due to the appropriate agency or authority.

(h) None of the Assets is an interest in any joint venture, partnership or other arrangement or contract which could be treated as a partnership for U.S. federal income tax purposes.

4.9 Environmental Matters. As of the date of this Agreement, there is no Proceeding or investigation pending or, to the knowledge of Seller, threatened, against Seller for alleged noncompliance with or liability under any environmental laws. Seller has made available to Purchaser copies of all material environmental reports with respect to inspections conducted by or on behalf of Seller, to the extent such reports are in the possession or control of Seller, with respect to any real property currently owned or leased by Seller or used in connection with the operation of the Business.

4.10 Financial Statements. Section 4.10 of the Disclosure Schedule sets forth (i) the unaudited consolidated balance sheet of Seller as of December 31, 2017 (the "Most Recent Balance Sheet"), (ii) the unaudited consolidated balance sheet of Seller as of June 30, 2018 and (iii) the unaudited consolidated profit and loss statement of Seller for the fiscal year ended December 31, 2017 and for the six-month period ended on June 30, 2018 (collectively, the "Financial Statements"; and the date of the Most Recent Balance Sheet, the "Most Recent Balance Sheet Date"). The Financial Statements have been prepared based on the books and records of the Seller, which, for the periods covered by the Financial Statements, have been maintained in accordance with United States generally accepted accounting principles applied on a consistent basis, and on that basis the Financial Statements present, to the knowledge of Seller, in all material respects, the financial position and results of operations of Seller as of the dates thereof and for the respective periods indicated.

4.11 No Undisclosed Liabilities. Seller has no liabilities, other than:

(a) liabilities provided for in the Financial Statements or the notes thereto;

(b) liabilities incurred in the ordinary course of business and consistent with past practices since the Most Recent Balance Sheet Date;

(c) liabilities set forth in Section 4.11 of the Disclosure Schedule;

(d) liabilities disclosed in, related to or arising under any Contract or other matter disclosed in this Agreement or set forth in the Disclosure Schedule;

(e) liabilities incurred in connection with this Agreement; and

(f) other liabilities that, individually or in the aggregate, would not reasonably be expected to be material to Seller or the Business, taken as a whole.

4.12 Compliance with Laws.

(a) Seller is, and has been during the two-year period immediately preceding the date of this Agreement in compliance in all material respects with all applicable laws that apply to the Business (including all Healthcare Laws), and during such period has not received any notice of noncompliance of such laws.

(b) Seller is not subject to a corporate integrity agreement, deferred prosecution agreement, consent decree or settlement agreement with any Governmental Entity with respect to the conduct of the Business.

(c) All practices of Seller regarding the collection, access, maintenance, transmission, use, and disclosure of "Individually Identifiable Health Information" in connection with the conduct and operations of the Business are and have been in compliance in all material respects with HIPAA.

4.13 Regulatory Matters.

(a) Seller has operated and currently is in compliance in all material respects with all applicable statutes and implementing regulations administered or enforced by the United States Food and Drug Administration ("FDA") or any similar Governmental Entity outside the United States (each, including the FDA, a "Regulatory Authority").

(b) The Company holds, and is operating in compliance in all material respects with, such licenses, permits, authorizations, certificates, franchises, consents and other approvals from any governmental body relating to the Business which are required in order for Seller to operate the Business as presently conducted (collectively, the "Regulatory Permits"), and is in compliance in all material respects with all such Regulatory Permits. The Seller has fulfilled and performed all of its material obligations with respect to the Regulatory Permits, and no event has occurred which allows, or after notice or lapse of time would allow, suspension, revocation or termination thereof or result in any other material impairment of the rights of the holder of any Regulatory Permit. All applications, notifications, product reports and submissions submitted in connection with any and all requests for a Regulatory Permit from any Regulatory Authority, were truthful and accurate in all material respects as of the date of submission and as of the date of the marketing authorization, and with respect to any marketing applications complete in all material respects as of the date of submission. To the knowledge of Seller, any necessary or required changes, modifications, updates, or corrections to such applications, notifications, and submissions have been submitted to any Regulatory Authority.

(c) All of Seller's products that are subject to the jurisdiction of a Regulatory Authority are being, and have been, designed, manufactured, imported, exported, processed, developed, labeled, stored, tested, marketed, promoted and distributed by or, on behalf of Seller in compliance in all material respects with all applicable requirements under any Regulatory Permit or law, including applicable statutes and implementing regulations administered or enforced by the Regulatory Authority.

(d) All preclinical studies and clinical trials conducted by or, to the knowledge of Seller, on behalf of Seller have been, and if still pending are being, conducted in compliance in all material respects with the research protocols applicable to each such study or test and all applicable law, including the United States Federal Food, Drug, and Cosmetic Act, its applicable implementing regulations at 21 C.F.R. Parts 50, 54, 56, 58, 812 and applicable good clinical practices or good laboratory practices, and 21 C.F.R. Parts 1000 through 1050. No clinical trial conducted by or, to the knowledge of Seller, on behalf of Seller has been terminated or suspended prior to completion, and no Regulatory Authority, or institutional review board or ethics committee, that has or has had jurisdiction over a clinical trial conducted by or on behalf of Seller has commenced, or to the knowledge of Seller, threatened to commence, any Proceeding investigation, audit, demand, or assessment to place a clinical hold order on, or otherwise terminate or suspend, any proposed or ongoing clinical investigation conducted or proposed to be conducted by or on behalf of Seller. No clinical trial conducted by or, to the knowledge of Seller, on behalf of Seller, has utilized the services of a clinical investigator or any other Person that was then or later became debarred or disqualified by a Regulatory Authority (including debarment under the Generic Drug Enforcement Act of 1992, 21 U.S. C. §§335a-335c).

(e) Seller has not had any product or manufacturing site subject to a Governmental Entity shutdown or import or export prohibition, nor received any written notice of inspectional observations from a Regulatory Authority, "warning letters," "untitled letters" or requests or requirements to make changes to the products or any of Seller's manufacturing processes or procedures, or similar written correspondence or notice from a Regulatory Authority in respect of the Business or Seller, as applicable, and alleging or asserting noncompliance with any applicable law, Regulatory Permit or such requests or requirements of a Regulatory Authority. To the knowledge of Seller, no contract manufacturer of Seller has had any manufacturing site subject to a Governmental Entity (including FDA or other Regulatory Authority) shutdown, or received any correspondence or notice from the any Regulatory Authority or any other Governmental Entity, alleging or asserting noncompliance with any applicable law, Regulatory Permit or requirements of a Governmental Entity for problems that could affect products manufactured by or on behalf of Seller.

(f) There are not and have not been any (i) recalls, field notifications, corrections, product replacements, warnings, "dear doctor" letters, investigator notices, safety alerts, reports of accidental radiation occurrences, notifications of defect or failure to comply under 21 C.F.R. Part 1003 or other notice of any Proceeding investigation, audit, demand, or assessment relating to an alleged lack of safety or regulatory compliance of the products issued by Seller ("Safety Notices") or (ii) material product complaints with respect to the medical device products. To the knowledge of Seller, there are no facts that would be reasonably likely to result in (A) a material Safety Notice with respect to the medical device products, (B) a material change in the labeling of any of the medical device products due to a safety or performance issue, or (C) a termination or suspension of developing and testing of any of the medical device products due to safety or performance issues. All adverse events occurring within or outside the United States have been submitted to the applicable Regulatory Authority in accordance with applicable law.

4.14 Transaction with Affiliates. Other than as set forth in Section 4.14 of the Disclosure Schedule, none of the Members, managers or officers of Seller: (a) own directly or indirectly any interest in, or serve as an officer or director of, any client, competitor, vendor or supplier of the Business; (b) have any loans or receivables outstanding to Seller; (c) are otherwise indebted to Seller with respect to the Business; (d) own any property, real or personal, tangible or intangible, required for or used in the Business; or (e) are owed any money or property by Seller, other than wages or salary earned (or expenses reimbursements owed) in the ordinary course of business.

4.15 Anti-Bribery. During the past two years, Seller has, and, to the knowledge of Seller, no representative of Seller has, (i) offered, made, paid or received any unlawful bribes, kickbacks or other similar payments to or from any Person (including any customer or supplier) or Governmental Entity, (ii) made or paid any contribution, directly or indirectly, to a domestic or foreign political party or candidate or (iii) made or paid any improper foreign payment (as defined in the Foreign Corrupt Practices Act (15 U.S.C. §§78dd-1 et seq.)), in each case ((i) through (iii)), in material violation of the Foreign Corrupt Practices Act or any other applicable anti-corruption Law.

4.16 Insurance. Seller has delivered or made available to Purchaser, a complete and correct list of each insurance policy (including the name of the carrier, the coverage limits and premium amounts) currently maintained in favor of Seller or the Business with a non-captive third party insurer (the "Insurance Policies"). Each of the Insurance Policies is in full force and effect. All premiums due and payable under the Insurance Policies have been paid on a timely basis and Seller is in compliance in all material respects with all its obligations under the Insurance Policies. As of the date of this Agreement, Seller has not received any written notice of cancellation, avoidance, rescission or material change in coverage with respect to any Insurance Policy. There are no material pending claims notified or asserted by Seller as to which any insurer under an Insurance Policy has denied coverage in whole or in part, or has reserved its rights to deny coverage in whole or in part.

ARTICLE 5. CLOSING

5.1 Closing and Closing Deliverables. The closing of the transactions contemplated hereby shall take place upon the execution of this Agreement (the "Closing" and the date on which the Closing takes place the "Closing Date").

5.2 Seller Closing Deliverables. Concurrently with this Agreement, Seller shall deliver to Purchaser:

(a) a Bill of Sale evidencing conveyance from Seller to Purchaser of the tangible personal property included in the Assets, in the form attached as Exhibit C hereto, duly executed by Seller;

(b) an Assignment and Assumption Agreement effecting the assignment to and assumption by Purchaser of the Assigned Contracts, in the form attached as Exhibit E hereto, duly executed by Seller;

(c) assignments transferring to Purchaser all of Seller's right, title and interest in and to the Intellectual Property Assets, in the forms attached as Exhibit F, duly executed by Seller;

(d) any and all other documents necessary or desirable for the transfer to Purchaser and proper recordation of ownership of the Assets, in form and substance satisfactory to Purchaser, each as duly executed by Seller;

(e) consulting agreements, duly executed by each of the Key Individuals, effective as of the Closing Date;

(f) an acknowledgment, waiver and release, as executed by:

(i) each Member and holder of any convertible securities listed on Schedule 5.2(f)(i), in the form attached as Exhibit D hereto;

(ii) the Persons identified on Schedule 5.2(f)(ii) confirming that, upon payment of no more than the amount specified next to such Person's name on Schedule 5.2(f)(ii), no amounts will be due or owing to such Person by the Seller, and related releases of claims by such Persons, in each case, in a form satisfactory to Purchaser;

(g) evidence satisfactory to Purchaser of the release by any Person who held a security interest in the Assets of all Encumbrances on the Assets;

(h) duly executed consents, in form and substance satisfactory to Purchaser, of all Governmental Entities and other Persons that are required (i) for the consummation of the transactions contemplated by this Agreement or (ii) in order to prevent a breach of, or a default under or a termination of any Assigned Contract;

(i) a certificate of the Secretary of State of the state of Delaware, dated as of a recent date, as to the due formation and good standing of the Seller and listing all documents of the Seller on file with said Secretary;

(j) a certificate of the Secretary of the Seller, dated as of the Closing Date and certifying on behalf of Seller: (A) that attached thereto is a true, correct and complete copy of each of the organizational documents of Seller, as in effect on the date of such certification; and (B) that attached thereto is a true, correct and complete copy of all resolutions adopted by the Seller's managers and Members authorizing the execution, delivery and performance of the sale, transfer and delivery of the Assets, this Agreement and the transactions contemplated hereby and that all such resolutions are still in full force and effect;

(k) the letter from Merck acknowledging the assignment by Seller to Purchaser of the Merck License Agreement; and

(l) such other Closing documents as Purchaser may reasonably require.

5.3 Purchaser Closing Deliverables. Concurrently with this Agreement, Purchaser shall deliver to Seller:

(a) the Closing Payment, in accordance with the terms of Section 2.1 and the funds flow memorandum (the "Funds Flow Memorandum") delivered by Seller to Purchaser prior to the Closing Date;

(b) an Assignment and Assumption Agreement regarding the Assumed Liabilities of Seller, attached as Exhibit E hereto, duly executed by Purchaser; and

(c) such other Closing documents as Purchaser may reasonably require.

ARTICLE 6. COVENANTS

6.1 Further Assurances. Upon the request of either party hereto, the other party will execute and deliver to the requesting party, or such party's nominee, all such instruments and documents of further assurance or otherwise, and will do any and all such acts and things as may reasonably be required to carry out the obligations of such party hereunder and to more effectively consummate the transactions contemplated hereby, including obtaining all consents and approvals from third parties as may be necessary.

6.2 Confidentiality. Seller agrees not to use or disclose to others, or permit the use or disclosure of, any and all Confidential Information (as defined herein) of Seller nor any Confidential Information of Purchaser that may have been furnished to Seller (including Confidential Information transmitted by each to representatives, accountants, counsel or advisors) in the course of negotiations relating to this Agreement and the business and financial reviews and investigations conducted pursuant hereto; provided, however, that Seller may disclose Confidential Information if, and to the extent that, such disclosure is required by any applicable law, subpoena, court order, regulation, or judicial or administrative process, provided that, to the extent practicable and permitted by applicable law or regulation, Seller will provide notice of such requirement to Purchaser for the purpose of enabling Purchaser to seek a protective order or otherwise prevent such disclosure. "Confidential Information" means information of Purchaser or Seller that is confidential and proprietary to Purchaser or Seller and not generally available to the public. Notwithstanding anything to the contrary, "Confidential Information" does not include information that (a) is or becomes generally available to the public other than as a result of a breach of this Agreement by Seller or any Member, (b) was available to Seller or Members on a non-confidential basis prior to its disclosure by Purchaser or Seller and (c) becomes available to Seller on a non-confidential basis from another source, provided that such other source is not known by Seller to be bound by, and to Seller's knowledge such disclosure does not breach, directly or indirectly, a confidentiality agreement between such other source and Purchaser.

6.3 Non-Interference. From and after the date of this Agreement and for a period of three (3) years from and after the Closing (the "Non-Interference Term") neither Seller nor any Key Individual will, anywhere in world, directly or indirectly:

(a) solicit for employment, recruit or hire, either as an employee or a consultant or independent contractor, any employee, consultant or independent contractor of Purchaser, Seller or any of their respective Affiliates who was an employee, consultant or independent contractor of Purchaser, Seller or any of their respective Affiliates (collectively, "Purchaser Entities") at any time prior to the end of the Non-Interference Term;

(b) interfere or attempt to interfere with any transaction, agreement, prospective agreement, business opportunity or business relationship in which any Purchaser Entity was involved, to the Knowledge of the Seller, at any time prior to the end of the Non-Interference Term; or

(c) otherwise engage or participate in any effort or act to induce any person to discontinue a relationship with any Purchaser Entity.

6.4 Non-Disparagement. From and after the date of this Agreement, no Key Individual shall, and each Key Individual agrees that it shall not, make or cause to be made or condone the making of any statement, comment or other communication, written or otherwise, that constitutes disparagement or criticism of, or otherwise be considered to be derogatory or detrimental to, or otherwise reflect materially adversely on, materially harm the reputation of, any Purchaser Entity or any of their respective owners, directors, officers, employees, agents or Affiliates or any of the products or services of any Purchaser Entity.

6.5 Purchaser's Efforts. From and after Closing, Purchaser shall use Commercially Reasonable Efforts to develop Product towards Marketing Authorization in the United States, Japan or the European Union for at least one indication and to commercialize such Product in the applicable territory following receipt of Marketing Authorization therein. Seller acknowledges that development activities toward Marketing Authorization for various countries may be conducted, in Purchaser's reasonable discretion, sequentially rather than simultaneously. Except as expressly provided in this Agreement, there shall be no obligations of development, commercialization or other diligence, either implied or construed, upon Purchaser.

6.6 Audit Rights. Purchaser shall make available, or cause to be made available to Seller, upon Seller's reasonable advance notice (but not less than three (3) business days' notice), during normal business hours and to the extent that doing so does not materially disrupt or interfere with the operations of Purchaser or the Business, Purchaser's records that are reasonably necessary to allow Seller to verify Purchaser's compliance with its payments obligations to Seller of the Subsequent Payments. All information disclosed pursuant to this Section 6.6 shall be treated as Confidential Information and shall not be disclosed to any third party or used for any purpose other than for the calculation of payments to be made to Seller and to determine Purchaser's compliance with the terms and conditions of this Agreement. Subject to this Section 6.6, the right to audit set forth herein shall include the right to interview personnel and review records as reasonably determined by the Seller, including sales analysis reports, accounting general ledgers, sublicense and distributor agreements, price lists, marketing materials, catalogs, audited financial statements, income tax returns, sales tax returns, inventory records, purchase records, and shipping documents, solely to the extent such records or access to such personnel is reasonably necessary to allow Seller to verify Purchaser's compliance with its payments obligations to Seller of the Subsequent Payments.

ARTICLE 7. INDEMNIFICATION

7.1 Indemnification by Seller and Purchaser; Limitations.

(a) From and after the Closing, Seller shall indemnify, defend and hold Purchaser, its Affiliates, and their respective directors, officers, representatives, employees and agents (collectively, the "Purchaser Indemnified Parties") harmless from and against any and all liability, loss, cost, expense, claim, lien or other damage, including, without limitation, reasonable attorneys' fees and expenses (all of the foregoing items for purposes of this Agreement are referred to as "Damages"), that may be incurred by Purchaser resulting or arising from or related to, or incurred in connection with: (i) the failure of Seller to assume, pay, perform and discharge any Retained Liability, (ii) any breach of any representation or warranty of Seller contained in this Agreement, (iii) any breach of any covenant, obligation or agreement of Seller contained in this Agreement, (iv) the liquidation and dissolution of Seller, including without limitation, any Damages incurred by Purchaser resulting from Seller's preferential payment of any liability or obligation prior to Seller's dissolution, or (v) any inaccuracy of the Funds Flow Memorandum.

(b) From and after the Closing, Purchaser shall indemnify, defend and hold Seller, its Affiliates, and their respective managers, officers, representatives, employees and agents (collectively, the "Seller Indemnified Parties") harmless from and against any and all Damages, that may be incurred by Seller resulting or arising from or related to, or incurred in connection with: (i) any breach of any representation, or warranty of Purchaser contained in this Agreement, (ii) any breach of any covenant, obligation or agreement of Purchaser contained in this Agreement, (iii) any Assumed Liability, or (iv) Liabilities arising out of or relating to any product liability, breach of warranty or similar claim for injury to person or property which resulted from the use or misuse of, or otherwise related to Product, used, manufactured, and sold/licensed after the Closing.

(c) Limitations:

(i) Other than with respect to the representations and warranties contained in Section 3.1 (Organization and Power), Section 3.2 (Authorization), 3.4 (Brokers and Finders), Section 4.1 (Title to Assets; Subsidiaries), and 4.8 (Taxes) (the "Excluded Representations"), neither Seller nor Purchaser shall have any liability under Section 7.1(a)(ii) and Section 7.1(b)(i), respectively, to indemnify any Purchaser Indemnified Party or Seller Indemnified Party, as applicable, for Damages until the aggregate amount of Damages exceeds Fifty Thousand and 00/100 ($50,000.00) Dollars (the "Threshold"), in which event the indemnifying party shall become liable only for amounts in excess of the Threshold.

(ii) Other than with respect to the Excluded Representations and the representations provided under Section 4.3, the aggregate indemnification obligation of Seller under Section 7.1(a)(ii) and of Purchaser under Section 7.1(b)(i), respectively, for Damages will not exceed the sum of (i) twenty percent (20%) of the Closing Payment, and (ii) twenty percent (20%) of the Subsequent Payments actually received by the Seller.

(iii) Subject to Section 7.1(c)(i)-(ii), notwithstanding anything in this Agreement to the contrary, absent Fraud, in no event will either Seller or Purchaser be required to repay any amount for Damages incurred under this Section 7.1 (including Damages arising out of the breach of any representation or warranty including an Excluded Representation) in excess of the Total Purchase Price actually paid to Seller pursuant to this Agreement. Seller's and Purchaser's obligation to indemnify and hold harmless the Purchaser Indemnified Parties or the Seller Indemnified Parties pursuant to this Section 7.1 shall survive until Seller is entitled to receive any Subsequent Payments under this Agreement.

(iv) The amount of any Damages of any Person subject to indemnification under this **ARTICLE 7** shall be reduced by the amount, if any, received by the indemnified party from any third Person (including, without limitation, any insurance company or other insurance provider (such amount being referred to herein as a "Third Party Reimbursement")), in respect of the Damages suffered thereby; provided, however, that nothing in this Section 7.1(c)(iv) shall be interpreted or construed as an obligation of any indemnified party hereunder to seek relief or indemnification from any third Person. If, after receipt by an indemnified party of any indemnification payment hereunder, such Person receives or becomes entitled to receive a Third Party Reimbursement in respect of the same Damages for which indemnification was made and such Third Party Reimbursement was not taken into account in assessing the amount of indemnification, then the indemnified party shall turn over all of such Third Party Reimbursement to the indemnifying party up to the amount of the indemnification paid pursuant hereto.

(v) Any indemnified party that becomes aware of Damages for which it seeks indemnification under this **ARTICLE 7** shall be required to use reasonable efforts to mitigate the Damages including taking any actions reasonably requested by the indemnifying party, and an indemnifying party shall not be liable for any Damages to the extent that it is attributable to the indemnified party's failure to mitigate.

(vi) No party hereto shall be liable under this **ARTICLE 7** for any incidental and consequential damages or special, punitive, exemplary or other similar damages other than (i) such damages that are shown be either (1) losses that would arise would be reasonably expected to arise as the result of a breach of any similar promise or undertaking or (2) losses reasonably foreseeable as a probable consequence of a breach of that promise or undertaking, and (ii) punitive and exemplary damages arising from a Third Party Claim (as defined below).

(vii) No party shall have any liability for any Damages which would not have arisen but for any alteration or repeal or enactment of any law after the Closing.

(viii) For purposes of this **ARTICLE 7** and notwithstanding anything to the contrary in this Agreement, all determinations of Damages in connection herewith shall be determined without regard to any materiality, material adverse effect or other similar qualification contained in or otherwise applicable to such representation or warranty.

7.2 Procedures for Indemnification.

(a) If any indemnified party receives notice of the assertion of any claim, the commencement of any Proceeding, or the imposition of any penalty or assessment by a third party in respect of which indemnity may be sought hereunder (a "Third Party Claim"), and the indemnified party intends to seek indemnity hereunder, then the indemnified party shall provide the indemnifying party with prompt written notice of the Third Party Claim. The failure by an indemnified party to notify an indemnifying party of a Third Party Claim shall not relieve the indemnifying party of any indemnification responsibility under this **ARTICLE 7**, unless the indemnifying party can prove that the failure materially prejudiced the ability of the indemnifying party to defend such Third Party Claim.

(b) The indemnified party shall have the right to control the defense or settlement of such Third Party Claim with counsel of its choosing; provided, however, that the indemnified party shall not settle or compromise any Third Party Claim without the indemnifying party's prior written consent, unless the terms of such settlement or compromise release the indemnified party or the indemnifying party from any and all liability with respect to the Third Party Claim. The indemnifying party shall be entitled (at the indemnifying party's expense) to participate in (but not control) the defense of any Third Party Claim with its own counsel.

(c) In the event the indemnified party elects not to defend the Third Party Claim, then the indemnifying party may defend such claim at indemnifying party's sole cost and expense with counsel selected by the indemnifying party, such counsel to be reasonably acceptable to the indemnified party. In such event, the indemnifying party shall not settle or compromise any Third Party Claim without the indemnified party's prior written consent, unless the terms of such settlement or compromise release the indemnified party from any and all liability with respect to the Third Party Claim.

(d) Notwithstanding the foregoing, in the event of a Third Party Claim by which a claim for indemnification is made against Seller pursuant to Section 7.1(a)(iii), Seller shall have the right to control the defense or settlement of such Third Party Claim with counsel of its choosing; provided, however, that Seller shall not settle or compromise any Third Party Claim without Purchaser's prior written consent, unless the terms of such settlement or compromise release Purchaser and its Affiliates from any and all liability with respect to the Third Party Claim. The indemnifying party shall be entitled (at the indemnifying party's expense) to participate in (but not control) the defense of any Third Party Claim described in this Section 7.2(d) with its own counsel.

(e) Any indemnifiable claim hereunder that is not a Third Party Claim shall be asserted by the indemnified party by promptly delivering notice thereof (the "Claim Notice") to the indemnifying party. If the indemnifying party: (i) agrees with the indemnified party with respect to such claim, a memorandum setting forth such agreement shall be prepared and signed by both parties or (ii) disputes the existence or the amount of such claim, the indemnifying party shall notify the indemnified party in writing (with reasonable specificity) within twenty (20) days following the indemnifying party's receipt of the Claim Notice (the "Response Notice") and the parties will negotiate in good faith to resolve such claim for up to thirty (30) days or such other period of time as the parties mutually agree. If the parties should then so agree with respect to such claim, a memorandum setting forth such agreement shall be prepared and signed by both parties. If no Response Notice is received by the indemnified party within twenty (20) days after the indemnifying party's receipt of the Claim Notice, the matter shall be deemed undisputed and the indemnifying party shall indemnify the indemnified party for the Damages. If the parties are unable to agree within the thirty (30) day negotiation period specified herein, either party can submit such matter for dispute resolution pursuant to Section 8.4.

7.3 Set-off. Subject to Section 7.2(e) and this Section 7.3, in addition to any and all other remedies hereunder or at law or in equity, Purchaser shall be entitled to recover any indemnification payment or other undisputed amounts due from Seller hereunder by retaining and setting off such payment or other amounts (whether or not such payment or amounts are liquidated or reduced to judgment) against the amounts representing the Subsequent Payments; provided, however, that Purchaser will not exercise any set-off rights: without providing advance written notice thereof to the Seller (a "Proposed Set-off Notice"), setting forth in reasonable detail the material facts providing a basis for such set-off as well as the amount proposed to be set-off. In the event that Seller and Purchaser cannot agree in writing with respect to a claim described in a Claim Notice pursuant to Section 7.2(e) or described in the Proposed Set-off Notice, Purchaser shall deposit such disputed amount in escrow with a mutually agreed-upon financial institution as escrow agent within 30 days following the end of the 30-day negotiation period set forth in Section 7.2(e), where such amount shall be held until the underlying dispute is resolved pursuant to the terms of this Agreement, after which the set-off provisions of this paragraph shall apply to such portion of the Subsequent Payments deposited in escrow. All costs and expenses of such escrow account shall be paid one half by Seller and one half by Purchaser. Notwithstanding the foregoing, (i) Purchaser shall only be obligated to deposit in escrow any portion of amounts payable to Seller which has been otherwise withheld by Purchaser pursuant to this Section 7.3, once such withheld amount exceeds $500,000, and (ii) the escrow agreement to be entered into by the parties and the escrow agent pursuant to this Section 7.3 shall set forth that any release of amounts held in escrow shall only be made pursuant to a joint written instruction signed by Seller and Purchaser.

7.4 No Subrogation. Following the Closing, Seller shall not have any right of indemnification, contribution or subrogation against any indemnified party with respect to any indemnification payment made by or on behalf of the Seller under Section 7.1.

7.5 Exclusive Remedy. Subject to Section 8.4(d), each party hereto agrees that indemnification under this **ARTICLE 7** shall be its sole and exclusive remedy solely with respect to any breach of this Agreement or any of the documents executed in connection with the Closing, other than claims for Fraud. In furtherance of the foregoing, each party hereto hereby waives, to the extent it may do so, any other rights or remedies that may arise at law or in equity, including under any applicable law.

ARTICLE 8. MISCELLANEOUS PROVISIONS

8.1 Announcements. No party shall issue any press release or make any public announcement relating to the subject matter of this Agreement without the prior written approval of the other party; provided, however, that after the Closing Purchaser may make (i) appropriate announcements to customers of the Business or (ii) any public disclosure it believes in good faith is required by applicable law.

8.2 Expenses. Each of the parties shall pay its own respective costs and expenses incurred or to be incurred by it in the negotiation and preparation of this Agreement and carrying out the transactions contemplated by this Agreement, including legal fees.

8.3 Assignment. The rights and obligations of the parties to this Agreement or any interest in this Agreement shall not be assigned, transferred, hypothecated, pledged or otherwise disposed of without the prior written consent of the nonassigning party which consent may be withheld in such party's sole discretion.

8.4 Applicable Law; Dispute Resolution; Waiver of Jury Trial.

(a) The terms, conditions and other provisions of this Agreement and any documents or instruments delivered in connection with it shall be governed and construed according to the internal laws of the State of Delaware.

(b) Each party irrevocably agrees that any Proceeding against it arising out of or in connection with this Agreement or the transactions contemplated by this Agreement or disputes relating hereto (whether for breach of contract, tortious conduct or otherwise) shall (subject to Section 8.4(d)) be brought exclusively in the Court of Chancery of the State of Delaware or, solely if such court lacks subject matter jurisdiction, the United States District Court for the District of Delaware, and the appellate courts having jurisdiction thereover (collectively, the "Chosen Courts"), and hereby irrevocably accepts and submits to the exclusive jurisdiction and venue of the Chosen Courts *in personam* with respect to any such Proceeding and waives to the fullest extent permitted by Law any objection that it may now or hereafter have that any such Proceeding has been brought in an inconvenient forum

(c) EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT TO ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREBY OR DISPUTES RELATING HERETO. EACH PARTY (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8.4(C).

(d) The parties agree that irreparable damage for which monetary damages, even if available, would not be an adequate remedy, would occur in the event that the parties do not perform their obligations under the provisions of this Agreement in accordance with its specified terms or otherwise breach such provisions. The parties acknowledge and agree that (a) each party shall be entitled to an injunction or injunctions, specific performance or other equitable relief to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof in any court of competent jurisdiction without proof of damages or otherwise, this being in addition to any other remedy to which it is entitled under this Agreement and (b) the right of specific enforcement is an integral part of the transactions contemplated by this Agreement and without that right, neither Seller nor Purchaser would have entered into this Agreement. The parties acknowledge and agree that a party seeking an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in accordance with this Section 8.4(d) shall not be required to provide any bond or other security in connection with any such order or injunction.

8.5 Headings; Counterparts. The section headings appearing in this Agreement are inserted only as a matter of convenience and in no way define, limit, construe or describe the scope or extent of such Section or in any way affect such Section. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

8.6 Entire Agreement; Amendment. This Agreement, together with all Exhibits hereto, constitutes the entire agreement among the parties pertaining to the subject matter hereof and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions, whether oral or written, of the parties, and there are no representations, warranties or other agreements among the parties in connection with the subject matter hereof except as set forth specifically herein or contemplated hereby. This Agreement may not be amended nor provisions waived except for by written instrument signed by the Purchaser and the Seller.

[*signature page to follow*]

IN WITNESS WHEREOF, the authorized representative of the parties to this Agreement have duly executed this Agreement effective as of the date first above written.

PURCHASER:

LUMOS PHARMA, INC.

By: /s/ Richard J. Hawkins
Name: Richard J. Hawkins
Title: Chief Executive Officer

Address: 4200 Marathon Blvd., Ste 200
Austin, Texas 78756

SELLER:

AMMONETT PHARMA LLC

By: /s/ Kevin Tully
Name: Kevin Tully
Title: Chief Executive Officer

Address: 3606 Salles Ridges Court
Midlothian, VA 23113

KEY INDIVIDUALS:

/s/ Michael Thorner
Michael Thorner

/s/ Roy Smith
Roy Smith

/s/ Kevin Tully
Kevin Tully

Annex I

DEFINED TERMS

For the purposes of this Agreement:

a) "Affiliate" of a Person means any affiliate, as defined in Rule 12b-2 under the Exchange Act.

b) "Commercially Reasonable Efforts" means the efforts and resources, consistent with the normal business practices of the Purchaser, used for the development of products owned by it or to which it has exclusive rights, which products are at a similar stage in their development or product life and are of similar market potential as the Product (collectively, "Similarly Situated Products"), taking into account efficacy, safety, regulatory authority approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, ability to finance the project, medical and clinical considerations, the likelihood of regulatory approval given the regulatory structure involved, the profitability of the product, including the royalties payable to licensors of patent or other rights, the costs of development, manufacture and marketing, and any other relevant information. For clarity, it is understood that Purchaser may, consistent with using "Commercially Reasonable Efforts," reduce efforts or application of resources, or delay or halt (temporarily or permanently) development, manufacturing and/or commercialization of the Product to the extent that such actions are consistent with the actions that Purchaser would typically take in light of the circumstances with respect to Similarly Situated Products, such as (without limitation) delay of clinical trials due to a clinical hold being imposed (e.g., due to identification or discovery of clinical safety issues that must be addressed before further research and development activities can resume) or delay in initiating subsequent clinical trials due to efficacy and/or safety issues, until such issues have been resolved, or cessation of manufacturing and marketing a Product due to safety or applicable commercial issues.

c) "Contracts" means any and all written or oral contracts or other agreements or understandings (including all schedules, annexes and exhibits thereto, and all amendments, waivers, change orders and statements of work or the like related thereto), of any nature, including evidences of indebtedness, loans, letters of credit, guarantees, leases, notes, indentures, security or pledge agreements, franchise agreements, master service contracts, purchase orders, work orders, statements of work, nondisclosure agreements, alliance/partner agreements, licenses, easements, permits, instruments, commitments, arrangements, understandings, powers of attorney, covenants not to compete, covenants not to sue, change of control agreements, employment agreements or settlement agreements to which the Seller is a party or by which any of the Seller's Assets are bound; provided, however, that, for purposes of this Agreement, Contracts do not include any Immaterial Contracts.

d) "Encumbrances" means all liens, encumbrances, claims, charges, options, security interests, pledges, rights of first refusal, or other title retention agreement.

e) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

f) "GMP" means the current good manufacturing practices and standards for the production of pharmaceutical intermediates and active pharmaceutical ingredients applicable to both commercial and investigational quantities of compounds (as applicable), as set forth in: (a) Parts 210 and 211 of Title 21 of the U.S. Code of Federal Regulations (21 CFR 210 and 21 CFR 211); and (b) European Community Directive 2003/94/EC and the Rules Governing Medicinal Products in the European Union, Volume 4 (Medicinal Products for Human and Veterinary Use: Good Manufacturing Practice), in each case, as may be amended from time to time after the Closing Date, and as interpreted by ICH Harmonised Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.

g) "Governmental Entity" means any (i) federal, state, local, foreign or other Governmental Entity, including any nation, state, commonwealth, province, territory, county, municipality, district or other juridical or political body; (ii) public primary, secondary or higher educational institution; or (iii) other governmental, self-regulatory or quasi-governmental entity of any nature (including any governmental division, department, agency, commission, instrumentality, official, organization, unit, body or entity and any court or other tribunal).

h) "Fraud" means that (i) to the actual knowledge of Seller, such representation and warranty was false when made, (ii) Seller had as such Seller's primary intention in making such representation and warranty to induce Purchaser to act or refrain from acting in such context, and (iii) Purchaser acted in justifiable reliance on such representation and warranty and was actually damaged as a result of same.

i) "Healthcare Laws" means Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh (Medicare), including specifically, the Ethics in Patient Referrals Act, as amended, 42 U.S.C. § 1395nn; Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (Medicaid); the Federal Health Care Program Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); the False Claims Act, 31 U.S.C. §§ 3729-3733 (as amended); the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Anti-Kickback Act of 1986, 41 U.S.C. §§ 51-58; the Civil Monetary Penalties Law, 42 U.S.C. §§ 1320a-7a and 1320a-7b; the Exclusion Laws, 42 U.S.C. § 1320a-7; HIPAA; laws related to the practice of pharmacy and the dispensing of medication, including the Controlled Substances Act (21 U.S.C. §§ 801 et seq.) and any corresponding state laws; Section 340B of the Public Health Services Act, as amended from time to time; all applicable implementing regulations, rules, ordinances, judgments, and orders for the foregoing; any similar state and local statutes, regulations, rules, ordinances, judgments, and orders; and all applicable laws related to licensing healthcare service providers providing the items and services that Seller provides, certificate of need, and reimbursement of healthcare service providers providing the items and services that Seller provides.

j) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191), the Health Information Technology for Economic and Clinical Health Act (Pub. L. No. 111-5) and their implementing regulations set forth at 45 CFR Part 160, 162 and 164.

k) "Indebtedness" means, with respect to any Person, all liabilities and obligations (including the outstanding principal amount of, accrued and unpaid interest on, fees, expenses and all other payment obligations (including any prepayment penalties or premiums payable as a result of the consummation of the transactions contemplated by this Agreement)), contingent or otherwise, in respect of, without duplication: (a) borrowed money or funded indebtedness or obligations issued in substitution or exchange for borrowed money or funded indebtedness; (b) indebtedness and obligations evidenced by any bond, note, debenture, or other debt security, guarantees, interest rate, currency or other hedging or swap arrangements; (c) all liabilities associated with capital leases, synthetic leases and sale leasebacks; (d) all guaranties, endorsements (except endorsements on checks) and other contingent obligations whether direct or indirect in respect of indebtedness or performance of others, including any obligation to supply funds to or in any manner to invest in, directly or indirectly, the debtor, to purchase indebtedness, or to assure the owner of indebtedness against loss, through an agreement to purchase goods, supplies or services for the purpose of enabling the debtor to make payment of the indebtedness held by such owner or otherwise; (e) obligations to reimburse issuers of any letters of credit with respect to amounts drawn thereunder, (f) any incentive or change in control payments (including any professional fees) accelerated or required to be made by Seller in connection with the transactions contemplated hereby to the extent not included in Transaction Expenses; (g) amounts accrued for annual and quarterly bonuses for the year ending December 31, 2017 and any accrued and unpaid payroll or severance liabilities (including payroll taxes), if not paid on or prior to the Closing Date to the extent not included in Transaction Expenses, (h) all obligations of the type referred to in clauses (a) though (g) of other persons secured by any Encumbrances on any property or asset of such Person (whether or not such obligation is assumed by such person).

l) "Immaterial Contract" means any contract that: (a) was entered into by the Seller in the ordinary course of business consistent with past practice; (b) has a term of less than sixty (60) days or may be terminated by the Seller (without penalty) within thirty (30) days of delivery of a termination notice by the Seller to the other party thereto; (c) does not contemplate or involve the payment of cash or other consideration in an amount or having a value in excess of $10,000, and (e) does not impose any guaranty, indemnity or similar obligation on the Seller; *provided that* no Contract pursuant to which Intellectual Property was created for, or transferred to, Seller shall be deemed an Immaterial Contract.

m) "Intellectual Property" means all intellectual property and other intangible property rights (including any related proprietary rights, interests and protections arising pursuant to the laws of any jurisdiction throughout the world), including (i) all patents, copyrights; database rights; trade secrets and other confidential business information, product names, trademarks, trade names, logos, slogans, domain names and service marks together with all goodwill related to the foregoing and any other intellectual property right recognized or protectable by any jurisdiction in the world and all registrations and applications for any of the foregoing and (ii) all technical, scientific, regulatory, clinical, medical, marketing, sales, financial and business information and data, know-how, structures, formulas, formulations, trade secrets, techniques, methods, processes, protocols, ideas, concepts, designs, compositions, devices, original works of authorship, technology, software, databases, algorithms, enhancements, derivative works, adaptations, discoveries and inventions (whether patentable or not).

n) "Key Individuals" means each of Michael Thorner, Roy Smith, and Kevin Tully.

o) "Knowledge", "knowledge" or "aware" means, with respect to the Seller, the actual knowledge of the Key Individuals, and the knowledge that the Key Individuals would have acquired after due inquiry of the employees of the Seller who would likely have knowledge of a matter in question given their employment responsibilities and functions. The words "know," "knowing" and "known" shall be construed accordingly.

p) "Merck" means Merck Sharp & Dohme Corp. and its Affiliates.

q) "Merck License Agreement" means the License Agreement by and between Seller and Merck Sharp & Dohme Corp., dated as of October 22, 2013, as amended, including all exhibits, schedules and attachments thereto.

r) "Orphan Drug Designations" means all orphan drug designations for Product that have been granted to Seller by Governmental Entities, including (a) the orphan drug designation, dated June 15, 2017, granted by the FDA to the Seller for Product for treatment of growth hormone deficiency and (b) the orphan drug designation, dated May 12, 2017, granted by the European Medicines Agency to the Seller for Product for treatment of growth hormone deficiency.

s) "Permitted Encumbrances" means collectively, (i) any restriction on transfer arising under applicable securities laws, (ii) Encumbrances for Taxes not yet delinquent or for Taxes that the taxpayer is contesting in good faith through appropriate proceedings, (iii) Encumbrances of lessors, lessees, sublessors, sublessees, licensors or licensees arising under lease arrangements or license arrangements, and (iv) Encumbrances arising in the ordinary course of business and not incurred in connection with the borrowing of money.

t) "Person" shall mean any individual, corporation, partnership, limited liability company, joint venture, association, joint-stock company, trust, unincorporated organization or governmental entity.

u) "Proceeding" means any suit, litigation, claim, formal or informal charge, complaint, action, hearing or other proceeding, whether judicial or administrative, before any Governmental Entity or arbitrator.

v) "Taxes" means any federal, state, county, local or foreign taxes, charges, fees, levies, or other assessments, including but not limited to all net income, gross income, sales and use, transfer, gains, profits, excise, franchise, real and personal property, gross receipt, capital stock, production, business and occupation, disability, employment, payroll, license, estimated, stamp, custom duties, severance or withholding taxes or charges imposed by a governmental entity, and includes any interest and penalties (civil or criminal) on or additions to any such taxes.

w) "Tax Return" means any return, statement, report or form (including estimated Tax returns and reports, withholding Tax returns and reports, amended returns, claims for refund, any schedule or attachment, and information returns and reports) required to be filed with respect to Taxes.

x) "Tax Sharing Agreement" means all written agreements the principal purpose of which is to provide for the allocation, apportionment, sharing or assignment of any Tax liability or benefit, or the transfer or assignment of income, revenues, receipts, or gains for the purpose of determining any Person's Tax liability, including any express or implied obligation to assume Taxes or to indemnify any other Person.

y) "Transaction Expenses" means to the extent not paid prior to the Closing, (a) all fees and expenses of Seller payable in connection with the transactions contemplated by this Agreement, including fees and expenses relating to the process of selling the Assets and the Business whether incurred in connection with this Agreement or otherwise, including all legal fees and expenses, accounting fees and expenses, Taxes and advisory fees and expenses, fees associated with the release and termination of any Encumbrance, investment banking fees and expenses, and financial advisory fees and expenses related to such sale process and (b) solely to the extent payable as a result of this Agreement or prior to the Closing, payments to be made on account of any stock options, incentive payouts, bonuses or any other similar instruments issued by Seller and any severance and other associated liabilities.

Exhibit B

SUBSEQUENT PAYMENTS

1. **Definitions**. Capitalized terms used in this Exhibit B shall have the meanings ascribed to them below or, if not defined below, the meanings set forth in the Agreement or the Merck License Agreement (as defined in the Agreement).

1.1 "**Agreement**" means the Asset Purchase Agreement to which this Schedule C is attached.

1.2 "**EOP2 Submission**" means the submission made to the FDA in advance of an "end of Phase 2" meeting with the FDA, as described in 21 C.F.R. 312.47(b)(iv).

1.3 "**Initiation**" has the meaning given to such term in the table set forth in Section 7.02 of the Merck License Agreement.

1.4 "**Licensed Product**" has the meaning given to such term in the Merck License Agreement.

1.5 "**Merck License Agreement**" has the meaning given to such term in the Agreement.

1.6 "**Net Sales**" has the meaning given to such term in the Merck License Agreement, with any references to "Licensee" changed to "Purchaser."

1.7 "**Phase IIb Trial**" means a Phase II Trial of a Licensed Product that is designed to support initiation of a Phase III Trial by finding the optimum dose at which the Licensed Product shows clinical efficacy in human patients with minimal side-effects.

1.8 "**Primary Royalty Period**" has the meaning given to such term in Section 3.2.

1.9 "**Seller Patents**" means (a) any patents or patent applications owned by Seller that are listed in Schedule 1.1(b) of the Agreement as of the Closing; (b) any substitutions, divisions, and continuations thereof, and any continuations-in-part thereof (but only to the extent that claims in such continuations-in-part are supported in the specification of the parent patent application), (c) any patents issued from the foregoing patent applications; (d) any reissues, renewals, registrations, confirmations, re-examinations and extensions of the foregoing patents; and (e) all foreign counterparts of the foregoing.

1.10 "**Tail Royalty Period**" has the meaning given to such term in Section 3.4.

1.11 "**Threshold**" has the meaning given to such term in Section 3.5.

1.12 "**Valid Claim**" has the meaning given to such term in the Merck License Agreement, with any references to "Compound Patent Rights" changed to "Seller Patent."

2. **Milestone Payments**.

2.1 **Development/Regulatory Milestones**. Purchaser shall pay to Seller the one-time milestone payments set forth in the table below if and when the listed milestone event is achieved by or on behalf of Purchaser (solely with respect to the first Licensed Product to achieve such milestone event). For clarity, once a milestone payment is paid, no further payments shall be owed if the applicable milestone event is later achieved with respect to other Licensed Products. Each such payment shall be due within thirty (30) days after achievement of such milestone event. Purchaser shall notify Seller within seven (7) Business Days after the occurrence of each milestone event giving rise to a payment obligation under this Section 2.1.

MILESTONE EVENT	PAYMENT
Initiation of first Phase IIb Trial for Licensed Product in Second Indication	$1,000,000
First EOP2 Submission for Licensed Product in First Indication	$2,000,000
First EOP2 Submission for Licensed Product in Second Indication	$1,000,000
Initiation of first Phase III Trial for Licensed Product for First Indication	$2,000,000
Initiation of first Phase III Trial for Licensed Product for Second Indication	$2,000,000
Acceptance for filing of first NDA for Licensed Product in the United States for First Indication	$2,000,000
Acceptance for filing of first NDA for Licensed Product in the United States for Second Indication	$3,000,000
Acceptance for filing of first application for Marketing Authorization for Licensed Product in either the European Union or a Major European Country for First Indication	$2,000,000
Acceptance for filing of first application for Marketing Authorization for Licensed Product in either the European Union or a Major European Country for Second Indication	$1,000,000
First Commercial Sale of Licensed Product in United States after receipt of Marketing Authorization for such Licensed Product in United States for First Indication	$4,000,000
First Commercial Sale of Licensed Product in United States after receipt of Marketing Authorization for such Licensed Product in United States for Second Indication	$3,000,000
First Commercial Sale of Licensed Product in European Union after receipt of Marketing Authorization for such Licensed Product in either the European Union or a Major European Country for First Indication	$3,000,000
First Commercial Sale of Licensed Product in European Union after receipt of Marketing Authorization for such Licensed Product in either the European Union or a Major European Country for Second Indication	$2,000,000
First Commercial Sale of Licensed Product in Japan after receipt of Marketing Authorization for such Licensed Product in Japan for First Indication	$2,000,000
First Commercial Sale of Licensed Product in Japan after receipt of Marketing Authorization for such Licensed Product in Japan for Second Indication	$1,000,000

The Parties acknowledge and agree that "First Indication" and "Second Indication" are used herein with the express intent of capturing the same meaning as in the table set forth in Section 7.02 of the Merck License Agreement.

2.2 **Sales Milestones**. Purchaser shall pay to Seller the one-time milestone payments set forth below if and when worldwide Net Sales of Licensed Products first exceed the indicated dollar value in a Calendar Year. Each such payment shall be due within thirty (30) days after the end of the Calendar Year in which such milestone event occurs. Purchaser shall promptly notify Seller of the occurrence of the first achievement of each such sales level.

GLOBAL ANNUAL NET SALES (US$)	PAYMENT
$100M	$5,000,000
$200M	$5,000,000
$300M	$5,000,000
$400M	$5,000,000
$500M	$10,000,000
$1B	$25,000,000

[***] Indicates that information has been omitted.

3. Royalty Payments.

3.1 During the Primary Royalty Period (as defined below) and subject to Section 3.5, Purchaser shall pay Seller incremental royalties on Net Sales of Licensed Products at tiered royalty rates determined by annual Net Sales, as follows

NET SALES (US$) DURING CALENDAR YEAR	ROYALTY RATE
[***]	**[***]**
[***]	**[***]**
[***]	**[***]**

3.2 **Primary Royalty Period**. Purchaser's obligation to pay royalties under Section 3.1 shall continue, on a country-by-country and product-by-product basis, until the expiration of royalty obligations under the Merck License Agreement with respect to the particular country and product, as set forth in Section 7.03(b) of the Merck License Agreement (the "**Primary Royalty Period**").

3.3 **Tail Royalty**. During the Tail Royalty Period (as defined below) and subject to Section 3.5, Purchaser shall pay Seller a royalty equal to **[***]** of Net Sales of Licensed Product.

3.4 **Tail Royalty Period**. Purchaser's obligation to pay royalties under Section 3.3 shall, on a country-by-country and product-by-product basis, commence on the end of the Primary Royalty Period and continue until **[***]** (the "**Tail Royalty Period**").

3.5 **Generic Erosion**. In the event that a generic version of a Licensed Product achieves **[***]** of total gross sales of Licensed Products in a particular country (as stated in IMS reports, for example in the United States, and in analogous reports in other countries) (the "**Threshold**"), (a) the royalties payable to Seller under Section 3.1 shall be reduced to **[***]** of Net Sales of Licensed Product in that particular country; and (b) the royalties payable to Seller under Section 3.3 shall be reduced to **[***]** of Net Sales of Licensed Product in that particular country; in each case for such time that the generic version of Licensed Product maintains the Threshold.

4. **Payment Terms**. Sections 7.04 of the Merck License Agreement shall apply *mutatis mutandis* to all payments owed under this Exhibit B.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Lumos Pharma, Inc.:

We consent to the incorporation by reference in the registration statement on Form S-3 (No. 333-226366) and Form S-8 (No. 333-178032, No. 333-184880, No. 333-186020, No. 333-203350, No. 333-234644, No. 333- 237590) of Lumos Pharma, Inc. of our report dated April 10, 2020, with respect to the balance sheets of Lumos Pharma, Inc. as of December 31, 2019 and 2018, the related statements of operations, changes in redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes, which report appears in the Form 8-K/A of Lumos Pharma, Inc. dated May 29, 2020.

Austin, Texas
May 29, 2020

Exhibit 99.2

LUMOS PHARMA, INC.

Financial Statements

December 31, 2019 and 2018

(With Report of Independent Registered Public Accounting Firm)

LUMOS PHARMA, INC.

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Lumos Pharma, Inc. (the Company) as of December 31, 2019 and 2018,and the related statements of operations, changes in redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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 financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

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

Austin, Texas
April 10, 2020

LUMOS PHARMA, INC.
Balance Sheets
December 31, 2019 and 2018
(In thousands, except share and per share amounts)

Assets	**2019**	**2018**
Current assets:		
Cash and cash equivalents	$ 4,952	$ 14,022
Prepaid and other current assets	117	202
Total current assets	5,069	14,224
Non-current assets:		
Right-of-use asset	373	—
Property and equipment, net of accumulated depreciation and amortization of $154 and $124, respectively	84	112
Total non-current assets	457	112
Total assets	$ 5,526	$ 14,336
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 365	$ 189
Accrued compensation	345	234
Other accrued liabilities	364	337
Current portion of lease liability	189	—
Total current liabilities	1,263	760
Long term liabilities:		
Operating lease liability	191	—
Total long-term liabilities	191	—
Total liabilities	1,454	760
Commitments and contingencies		
Redeemable convertible preferred stock:		
Series B redeemable convertible preferred stock, par value $0.0001; 9,966,288 stock authorized, issued and outstanding as of December 31, 2019 and 2018; stated at accreted redemption value	41,631	39,592
Series A redeemable convertible preferred stock, par value $0.0001; 11,204,513 stock authorized, issued and outstanding as of December 31, 2019 and 2018; stated at accreted redemption value	21,904	20,903
Stockholders' deficit:		
Common stock, $0.0001 par value; 36,000,000 shares authorized as of December 31, 2019 and 2018; and 9,003,433 and 10,283,437 shares issued and outstanding as of December 31, 2019 and 2018, respectively	1	1
Treasury stock, at cost, 1,350,000 shares held as of December 31, 2019, none held at December 31, 2018	—	—
Additional paid-in capital	213	12
Accumulated deficit	(59,677)	(46,932)
Total stockholders' deficit	(59,463)	(46,919)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 5,526	$ 14,336

See accompanying notes to financial statements.

LUMOS PHARMA, INC.
Statements of Operations
Years ended December 31, 2019 and 2018
(In thousands)

	2019	2018
Operating expenses:		
Research and development	$ 5,669	$ 5,253
In-process research and development	—	3,500
General and administrative, including stock-based compensation of $179 and $199, respectively	4,147	2,533
Total operating expenses	9,816	11,286
Loss from operations	(9,816)	(11,286)
Other income, net:		
Interest and other income, net	111	124
Net loss	$ (9,705)	$ (11,162)

See accompanying notes to financial statements.

LUMOS PHARMA, INC.

Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit

Years ended December 31, 2019 and 2018

(In thousands, except share amounts)

	Series B redeemable convertible preferred stock		Series A redeemable convertible preferred stock		Common stock		Treasury stock, at cost		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2017	9,966,288	$ 37,553	11,204,513	$ 19,901	10,083,437	$ 1	—	$ —	$ (221)	$ (32,729)	$ (32,949)
Exercise of common stock options	—	—	—	—	200,000	—	—	—	34	—	34
Net loss	—	—	—	—	—	—	—	—	—	(11,162)	(11,162)
Stock-based compensation	—	—	—	—	—	—	—	—	199	—	199
Accretion of preferred stock to current redemption value	—	2,039	—	1,002	—	—	—	—	—	(3,041)	(3,041)
Balance, December 31, 2018	9,966,288	39,592	11,204,513	20,903	10,283,437	1	—	—	12	(46,932)	(46,919)
Exercise of common stock options	—	—	—	—	69,996	—	—	—	22	—	22
Treasury stock purchase, at cost	—	—	—	—	(1,350,000)	—	1,350,000	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(9,705)	(9,705)
Stock-based compensation	—	—	—	—	—	—	—	—	179	—	179
Accretion of preferred stock to current redemption value	—	2,039	—	1,001	—	—	—	—	—	(3,040)	(3,040)
Balance, December 31, 2019	9,966,288	$ 41,631	11,204,513	$ 21,904	9,003,433	$ 1	1,350,000	$ —	$ 213	$ (59,677)	$ (59,463)

See accompanying notes to financial statements.

LUMOS PHARMA, INC.
Statements of Cash Flows
Years ended December 31, 2019 and 2018
(In thousands)

	2019	2018
Cash flows from operating activities:		
Net loss	$ (9,705)	$ (11,162)
Adjustments to reconcile net loss to net cash used in operating activities:		
In-process research and development	—	3,500
Depreciation and amortization	30	33
Amortization of right-of-use asset and change in operating lease liability	7	—
Stock-based compensation	179	199
Changes in operating assets and liabilities:		
Other current assets	85	(40)
Accounts payable	176	(74)
Accrued liabilities	138	354
Net cash used in operating activities	(9,090)	(7,190)
Cash flows from investing activities:		
Acquisition of in-process research and development	—	(3,500)
Purchases of property and equipment	(2)	(1)
Net cash used in investing activities	(2)	(3,501)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	22	34
Net cash provided by financing activities	22	34
Net decrease in cash and cash equivalents	(9,070)	(10,657)
Cash and cash equivalents at beginning of period	14,022	24,679
Cash and cash equivalents at end of period	$ 4,952	$ 14,022

See accompanying notes to financial statements.

(1) The Company

Lumos Pharma, Inc. ("Lumos" or the "Company") is a clinical-stage biopharmaceutical company focused on the identification, acquisition and in-license, development, and commercialization of novel products for the treatment of rare diseases. Lumos' mission is to develop new therapies for people with rare diseases, prioritizing its focus where the medical need is high, and the pathophysiology is clear. The Company's principal offices are located in Austin, Texas.

Since inception, the Company has devoted substantially all of its efforts and resources to identifying and developing its product candidates, recruiting personnel, and raising capital. The Company has never generated revenue and has not yet commenced commercial operations.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation

The accompanying financial statements of Lumos have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included.

(b) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Such management estimates include those related to accruals of research and development related expenses, fair value of common stock and stock-based compensation, and valuation of deferred tax assets. Actual results could differ significantly from those estimates.

(c) Risks and Uncertainties

The product candidates being developed by the Company require approvals from the U.S. Food and Drug Administration (the "FDA") and/or foreign regulatory agencies prior to commercial sales. There can be no assurance that the Company's product candidates will receive the necessary approvals. If the Company is denied regulatory approval of its product candidates, or if approval is delayed, it may have a material adverse impact on the Company's business, results of operations, and its financial position.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery and development of drug candidates, raising additional capital, development of competing drugs and therapies, protection of proprietary technology and market acceptance of the Company's products. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company's future success.

(d) Concentrations of Credit Risk

The Company's cash and cash equivalents are held by a financial institution in the United States that potentially subjects the Company to a concentration of credit risk. The Company's cash deposits generally exceed federally insured limits. Management believes that the financial institution is financially sound and, accordingly, does not believe the Company is subject to substantial credit risk. The Company has not experienced any significant credit losses to date.

(e) Cash and Cash Equivalents

Cash and cash equivalents, which consist primarily of amounts held in checking, savings, and money market accounts, are stated at fair value. The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

(f) Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets which range from 3 to 8 years. Repairs and maintenance that do not extend the life or improve an asset are expensed as incurred. Upon retirement or sale, the cost of disposed assets and their related accumulated depreciation are removed from the balance sheet. Any gain or loss is credited or charged to operations.

(g) Impairment of Long-Lived Assets

The Company evaluates its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of these assets is measured by a comparison of their carrying amounts to future undiscounted cash flows the assets are expected to generate. If long-lived assets are considered to be impaired, the impairment to be recognized equals the amount by which the carrying value of the assets exceeds their fair value and is recorded in the period the determination is made. There was no impairment of long-lived assets in the years ended December 31, 2019 and 2018.

(h) Research and Development ("R&D") Expenses

R&D expenses are expensed as incurred. Amounts incurred in connection with license agreements are also included in R&D expenses. Advance payments for goods or services to be rendered in the future for use in R&D activities are deferred and recorded as a prepaid asset. The deferred amounts are expensed as the related goods are delivered or the services are performed.

The Company records the expenses associated with research preclinical studies, clinical trials, and manufacturing development, as incurred. These expenses are a significant component of the Company's R&D expenses, as a substantial portion of the Company's ongoing R&D activities are conducted by third-party service providers.

(i) Asset Acquisition

The Company adopted ASU 2017-01, Business Combinations: Clarifying the Definition of a Business ("ASU 2017-01") in 2018 which resulted in the asset purchase agreement described in Note 10(b)(iii) being accounted for as an asset purchase. The acquisition expense for the purchase of the in-process research and development were expensed to R&D expenses in 2018. The Company has no reasonable expectation that there is an alternative future use of the asset purchased at this time and therefore, the purchase of the in-process R&D was immediately charged to expense.

(j) Series A and B Redeemable Convertible Preferred Stock

The Company accounts for its preferred stock subject to possible conversion in accordance with ASC 480, Distinguishing Liabilities from Equity ("ASC 480"). Stock subject to mandatory conversion (if any) is classified as a liability instrument and is measured at fair value. Conditionally convertible stock (including stock that features conversion rights that are either within the control of the holder or subject to conversion upon the occurrence of uncertain events not solely within the Company's control) is classified as temporary equity. At all other times, stock is classified as stockholders' equity. The Company's preferred stock features certain redemption rights that are considered by the Company to be outside of the Company's control and subject to the occurrence of uncertain future events.

Accordingly, at December 31, 2019 and 2018, the preferred stock subject to contingent redemption is presented as temporary equity, outside of the stockholders' deficit section of the Company's balance sheet. The carrying amount is at the issuance date fair value in accordance with ASR 268, Presentation in Financial Statements of Redeemable Preferred Stocks ("ASR 268") and adjusted to its maximum redemption amount due to its redemption features in accordance with ASC 480-10-S99-3A. The conversion feature of the Series A and Series B Redeemable Convertible preferred stock may be subject to certain antidilution provisions, which, if exercised, would require the Company to seek stockholder approval to increase the number of common shares authorized. For more information related to the redemption and conversion features of preferred stock, see Note 6.

(k) Stock-Based Compensation

The fair value of each option grant is estimated at the date of grant using the Black Scholes pricing model. Volatility is based on average historical volatilities for public companies in similar industries over the expected term of the option. The expected term of options represents the period of time that options granted are expected to be outstanding. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The Company utilized the probability weighted expected return method to estimate the fair value of each class of common and preferred stock. The valuation methodology included estimates and assumptions that require the Company's judgment. Significant inputs used to determine estimated fair value of the stocks include the equity value of the Company and expected timing of a liquidity event or other outcomes. Changes in these subjective unobservable inputs would result in an impact to the fair value measurement of the Company's shares and stock option fair value. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The Company recognizes the compensation expense either immediately or up to 4 years (the vesting periods) on a straight-line basis over the vesting period, and recognizes forfeitures as they occur.

(l) Income Taxes

The Company accounts for deferred income taxes using the asset and liability method. Under this method, deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. Temporary differences are then measured using the enacted tax rates and laws. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that is more likely than not to be realized. Determining the appropriate amount of valuation allowance requires management to exercise judgment about future operations.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on the technical merits, as the largest amount of benefits that is more likely than not to be realized upon the ultimate settlement. The Company's policy is to recognize interest and penalties related to the unrecognized tax benefits as a component of income tax expense. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

(3) New Accounting Pronouncements

(a) Leases

In February 2016, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2016-02 (Topic 842), Leases, which requires lessees to recognize right-of-use assets and liabilities on the balance sheet and disclose key information about leasing arrangements. The Company adopted the standard on January 1, 2019 using the modified retrospective method applying the new standard to all leases existing on the date of initial application. The Company has elected that the date of the initial application, January 1, 2019, will be the effective date. Consequently, financial information is not updated, and disclosures required under the new standard are not provided for dates and periods prior to January 1, 2019.

The Company elected the "package of practical expedients", which permits the Company not to reassess its prior conclusions about lease identification, lease classification and initial direct costs under the new standard. The Company did not elect to apply the use-of-hindsight or the practical expedient pertaining to land easements; as the latter is not applicable to the Company.

Upon adoption of the standard, the Company recorded a lease liability and right-of-use asset of $555,000 associated with their lease. There was no material impact to the statement of operations. Refer to Note 5 for additional discussion regarding the lease liability and right-of-use asset as of December 31, 2019.

(b) Fair Value Measurement

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure for Fair Value Measurement ("ASU 2018-13"), which modifies the disclosure requirements on fair value measurements. ASU 2018-13 is effective for all entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, with partial early adoption permitted for eliminated disclosures. The method of adoption varies by the disclosure. The Company is currently evaluating the impact that adopting this guidance will have on the financial statements and related disclosures.

(c) Codification Improvements

In July 2018, the FASB issued ASU 2018-09, Codification Improvements ("ASU 2018-09"), which made minor amendments to the codification in order to correct errors, eliminate inconsistencies and provide clarifications in current guidance. ASU 2018-09 amends Subtopics 470-50, Debt Modifications and Extinguishments, and 718-40, Compensation-Stock Compensation-Income Taxes, among other Topics amended within the update. Several of the Topics within the ASU were effective immediately upon issuance of ASU 2018-09, however, some amendments require transition guidance which is effective for nonpublic business entities for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact that adopting this guidance will have on the financial statements and related disclosures.

(d) Definition of a Business

In January 2017, the FASB issued ASU 2017-01, which amends the current definition of a business. Under ASU 2017-01, to be considered a business, an acquisition would have to include an input and substantive process that together significantly contributes to the ability to create outputs. ASU 2017-01 further states that when substantially all of the fair value of gross assets acquitted is concentrated in a single asset (or a group of similar assets), the assets acquired would not represent a business. The new guidance also narrows the definition of the term "outputs" to be consistent with how it is described in Topic 606, Revenue from Contracts with Customers. The change to the definition of a business will likely result in more acquisitions being accounted for as asset acquisitions. The Company adopted ASU 2017-01 in 2018 which resulted in the asset purchase agreement described in 10(b)(iii) being accounted for as an asset purchase.

(4) Liquidity and Capital Resources

Since inception and as of December 31, 2019, the Company has incurred operating losses, has negative cash flows from operations and has not generated revenue. The Company expects to incur significant expenses, increased operating losses, and negative cash flows for the foreseeable future. The Company expects its expenses to increase in connection with conducting additional nonclinical studies, initiating clinical trials of its product candidates, seeking regulatory approval and marketing authorizations for its product candidates, and commercializing these product candidates, if approved. The Company may never achieve profitability and, as such, will need to raise additional capital. Accordingly, it will seek to fund its operations through public or private equity or debt financings, collaborations, grants, or other sources none of which can be assured, if and when necessary. The Company recorded net losses of $9.7 million and $11.2 million for the years ended December 31, 2019 and 2018, respectively. The Company had an accumulated deficit of $59.7 million and net working capital of $4.0 million as of December 31, 2019. The Company has funded its operations primarily through the sale and issuance of redeemable convertible preferred and common stock. As of December 31, 2019, the Company had cash and cash equivalents consisting of $5.0 million. After the completion of the Merger (as defined in Note 13) on March 18, 2020, the combined company will have cash reserves which will be sufficient to meet liquidity and capital requirements.

(5) Leases

The Company has a lease agreement for office space in Austin, Texas, which commenced in November 2014, and has been extended through November 30, 2021. There are no renewal provisions or variable lease payments for this lease.

The Company records the lease liability based on the present value of lease payments over the lease term using an incremental borrowing rate to discount its lease liability, as the rate implicit in the lease is not readily determinable. The right-of-use asset is recognized on a straight-line basis over the remaining lease term. To compute the present value of the lease liability, the Company used a discount rate of 5%. The remaining lease term as of December 31, 2019 is 1.92 years.

The Company does not separate lease components from non-lease components. The Company's lease agreement does not contain any residual value guarantees or restrictive covenants.

Future minimum lease payments under the non-cancelable operating lease as of December 31, 2019 (in thousands) are as follows:

For the year ended December 31:		
2020	$	204
2021		195
Thereafter		—
Total future minimum lease payments		399
Less: Imputed interest		(19)
Total	$	380

The undiscounted non-cancelable future minimum lease payments for the operating lease under the prior lease standard at December 31, 2018 (in thousands) are as follows:

For the year ended December 31:		
2019	$	196
2020		204
2021		195
Thereafter		—
Total	$	595

For the years ended December 31, 2019 and 2018, the Company incurred $201,000 and $192,000, respectively in operating lease expense under its noncancelable operating lease, which has been included in general and administrative in the statement of operations. In 2019, cash paid for operating leases was $196,000.

(6) Property and Equipment, Net

Property and equipment, net consist of the following (in thousands):

	December 31	
	2019	**2018**
Furniture and equipment	$ 119	$ 119
Leasehold improvements	64	64
Computer equipment	51	49
Software	4	4
Property and equipment, gross	238	236
Less accumulated depreciation and amortization	(154)	(124)
Property and equipment, net	$ 84	$ 112

Depreciation and amortization expense was $30,047 and $33,076 for the years ended December 31, 2019 and 2018, respectively. All of the Company's long-lived assets are located in the United States.

(7) Series A and Series B Redeemable Convertible Preferred Stock

In January 2014, the Company raised $6.5 million through the issuance of 4,353,928 shares of Series A Preferred Stock at $1.49 per share through the "Initial Closing" of the Series A round. A "Second Closing" in May 2014 raised an additional $1.0 million through the issuance of 669,835 shares of Series A Preferred Stock at $1.49 per share.

In 2015, the Company raised an additional $3 million with a "Third Closing," which was funded in three tranches through the issuance of a total of 1,826,823 shares of Series A Preferred Stock at $1.64 per share.

In December 2015, the Company received another $3.25 million of funding due to the trigger of milestone closing provisions of the Initial Closing agreement ("Milestone Closing") and issued 2,176,963 shares of Series A Preferred Stock at $1.49 per share.

A second tranche of the Milestone Closing occurred in February 2016, and the Company issued 2,176,964 shares of Series A Preferred Stock at the issue price of $1.49 per share and received gross proceeds of $3.25 million.

In April 2016, the Company issued 9,966,288 shares of Series B Preferred Stock, at an issuance price of $3.41 per share and received gross proceeds of $34.0 million.

Series A Preferred Stock and Series B Preferred Stock consist of the following (in thousands, except share amounts):

	December 31	
	2019	**2018**
Series B:		
Shares authorized	9,966,288	9,966,288
Shares outstanding	9,966,288	9,966,288
Liquidation preference	$ 41,631	$ 39,592
Series A:		
Shares authorized	11,204,513	11,204,513
Shares outstanding	11,204,513	11,204,513
Liquidation preference	$ 21,904	$ 20,903

Significant provisions of the Series A Preferred Stock and Series B Preferred Stock are as follows:

(a) Dividends

From the date of issuance of shares of Series A Preferred Stock, dividends shall accrue equal to 6% of the Original Issue Price. The Original Issue Price for the Series A Initial Closing, Second Closing, Third Closing, and Milestone Closing is $1.49 per share (the "Series A Original Issue Price").

The Company shall not pay any dividends on stock of any other class or series of stock in any calendar year unless the holders of shares of Series B Preferred Stock then outstanding shall first receive a dividend on each share of outstanding stock of Series B equal to 6% of the Original Issue Price. The Original Issue Price for the Series B is $3.41 per share (the "Series B Original Issue Price").

The Company has no obligation to pay such dividends except when, as and if declared by the board of directors (the "Board"). If after the dividends in the full preferential amount described above have been paid in any calendar year, the Board shall declare additional dividends, then such additional dividends shall be declared pro rata on the shares of common and preferred stock on a pari passu basis according to the number of shares of common stock held by such holders. For this purpose, each holder of shares of preferred stock is to be treated as holding the greatest whole number of shares of common stock then issuable upon conversion of all shares of preferred stock held by such holder. Since inception, the Company has not declared or paid any dividends.

(b) Voting

Each holder of outstanding shares of preferred stock has voting rights equal to an equivalent number of shares of common stock into which it is convertible and votes together as one class along with the common stock. The holders of the shares of preferred stock have the right to vote on all significant matters as to which holders of shares of common stock have the right to vote.

For as long as at least 15% of the authorized shares of preferred stock remain outstanding, the Company must obtain the affirmative vote or written consent by at least a majority of the then outstanding shares of Series A and Series B Preferred Stock, along with Board consent to consummate significant transactions, including, but not limited to, the authorization and issuance of additional stock or stock classes, changing the legal form of the Company, and the approval of a deemed liquidation event.

(c) Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, the holders of shares of Series B Preferred Stock are entitled to be paid out of the assets of the Company before any payment shall be made to the holders of shares of Series A Preferred Stock or common stock. The holders of the shares of Series B Preferred Stock shall receive the greater of i) the Series B Original Issue Price per share plus all unpaid accruing dividends, declared or not, on such shares of preferred stock or ii) the amount per share that would have been payable had all preferred stock been converted into common stock immediately prior to such liquidation, dissolution, or winding up. After the payments to the holders of Series B Preferred Stock, the holders of shares of Series A Preferred Stock are entitled to be paid out of the assets of the Company before any payment shall be made to the holders of shares of common stock. The holders of the shares of Series A Preferred Stock shall receive the greater of i) the Series A Original Issue Price per share plus all unpaid accruing dividends, declared or not, on such shares of preferred stock or ii) the amount per share that would have been payable had all preferred stock been converted into common stock immediately prior to such liquidation, dissolution, or winding up. Liquidation payments to preferred stockholders are payable in preference and priority to any payments made to the holders of the then outstanding shares of common stock and any equity securities ranking junior to the preferred stock. After the payments to the holders of Series B Preferred Stock and Series A Preferred Stock, the remaining assets of the Company available for distribution shall be distributed among the holders of shares of Series B Preferred Stock, Series A Preferred Stock and the common stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock immediately prior to such liquidation, dissolution or winding up of the Company; provided, however, that each holder of Series A Preferred Stock and Series B Preferred Stock shall not receive aggregate distributions greater than three times the application Original Issue Price.

(d) Redemption

Upon the request from the holders of a majority of the outstanding shares of preferred stock, including the holders of at least 32.3% of the outstanding shares of Series B Preferred Stock, the Series A and B Preferred Stock would be redeemed by the Company at a price per share equal to the Series A and Series B Preferred Stock Original Issue Price plus all unpaid accruing dividends, declared or not, in three equal annual installments commencing not more than 60 days after the sixth anniversary of issuance of the shares of Series B Preferred Stock in April 2016. Holders may elect a redemption request at any time after April 4, 2023 or upon a deemed liquidation event. The Company has classified the Series A and B Preferred Stock as temporary equity outside of the Stockholders' Deficit based on the premise that these instruments provide the holder with the option to redeem at a determinable price, and have reflected the value to accreted redemption value at the end of the reporting period.

(e) Conversion

Each share of Series A and Series B Preferred Stock is convertible at the option of the holder, at any time into that number of fully paid and nonassessable shares of common stock determined by dividing the Original Issue Price of the convertible preferred stock by the conversion price in effect on the date of conversion.

Conversion is automatic immediately upon i) the Company's sale of common stock in a firm commitment underwritten public offering of at least two times the Series B Original Issue Price (subject to adjustments for stock dividends, splits, combinations, and similar events) provided that the proceeds total at least $40,000,000, or ii) the election of the holders of a majority of the then outstanding shares of preferred stock.

(8) Common Stock

The following is a summary of the Company's common stock shares at December 31:

	December 31	
	2019	**2018**
Common stock:		
Shares authorized	36,000,000	36,000,000
Shares outstanding	9,003,433	10,283,437
Treasury stock shares	1,350,000	0

The holders of common stock are entitled to receive distributions out of any assets legally available, subject to the prior rights and preferences of holders of all classes of shares outstanding.

On September 27, 2019, the Company repurchased 1,350,000 shares of common stock from two stockholders for an aggregate amount of $20. The repurchase was in conjunction with the anticipated Merger described in Note 13. If the Merger was not consummated, the repurchased shares would have been returned to the stockholders from which the shares were purchased without additional consideration.

(9) Stock-Based Compensation

In 2012, the Company adopted the Lumos Pharma, Inc. 2012 Equity Incentive Plan ("2012 Plan"), and in 2016 the Company adopted a 2016 Stock Plan ("2016 Plan" and together with the 2012 Plan, the "Plans"). The Plans provide incentives to employees, consultants, and nonemployee directors of the Company by providing issuance of incentive stock options, nonstatutory stock options, stock appreciation rights, stock warrants, and restricted stock and incentive awards of common stock or any other class of equity authorized by the Company and designated by the board of directors as incentive equity.

In conjunction with the Series B financing, the maximum number of shares of common stock that can be issued were increased by 2,359,490, to a total of 3,711,490. The number of shares of common stock reserved is 920,907 and 2,790,583 for the 2012 Plan and the 2016 Plan, respectively.

Common stock has been reserved for issuance under such plans as of December 31, 2019, of which 1,779,234 shares are available for future grants. The Company's stock options issued to date have variable vesting schedules, with a typical four years vesting schedule in which 25% of the stock vest on the one-year anniversary and the remaining shares vest over equal monthly installments thereafter. All awards expire ten years from the date of grant.

The weighted-average assumptions for 2019 and 2018 grants are provided in the following table.

	2019	**2018**
Valuation assumptions		
Expected dividend yield	0%	0%
Expected volatility	90%	90%
Expected term (years)	6.02	5.92
Risk-free interest rate	1.8%	2.8%

The following tables summarize stock option activity under the 2012 Plan and the 2016 Plan, which, to date, has consisted solely of stock options to employees:

	Number of Shares	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	Aggregate instrinsic value
Outstanding at December 31, 2017	2,158,863	$ 0.46	7.85	-
Granted	473,252	0.32		-
Exercised	(200,000)	(0.17)		-
Forfeited	(245,646)	(0.18)		-
Outstanding at December 31, 2018	2,186,469	$ 0.49	7.67	-
Options exercisable at December 31, 2018	1,377,963	$ 0.49	7.22	-
Outstanding at December 31, 2018	2,186,469	$ 0.49	7.67	-
Granted	200,000	0.24		-
Exercised	(69,996)	(0.32)		-
Forfeited	(737,650)	(0.61)		-
Outstanding at December 31, 2019	1,578,823	$ 0.41	6.96	-
Options exercisable at December 31, 2019	1,184,013	$ 0.43	6.41	-

A summary of the status of the Company's nonvested shares as of December 31, 2019 and 2018, and changes during the years ended December 31, 2019 and 2018 is presented below:

Nonvested shares	Shares	Weighted average grant-date fair value
Balance at December 31, 2017	821,756	$ 0.61
Granted	473,252	0.32
Vested	(486,502)	(0.54)
Balance at December 31, 2018	808,506	$ 0.48
Granted	200,000	0.24
Vested	(457,317)	(0.48)
Forfeited	(156,379)	(0.55)
Balance at December 31, 2019	394,810	$ 0.33

Total stock-based compensation recognized from the Plans in the years ended December 31, 2019 and 2018, was $178,767 and $198,676, respectively, which is recorded as general and administrative expense in the statements of operations.

As of December 31, 2019, the total unrecognized compensation expense related to unvested employee awards was $178,119 which the Company expects to recognize over an estimated weighted average period of 2.65 years.

(10) Income Taxes

The differences between the actual income tax benefit and the amount computed by applying the statutory federal tax rate of 21% to the loss before taxes are as follows (amounts in thousands):

	Year ended December 31,			
	2019		2018	
	Amount	Tax Rate	Amount	Tax Rate
Income tax benefit using statutory rate	$ (2,036)	21%	$ (2,345)	21%
Permanent differences	263	(3%)	(5)	-
Return to provision adjustments	(4)	-	-	-
Change in tax rate	-	-	-	-
Change in valuation allowance	1,777	(18%)	2,350	(21%)
Income tax expense (benefit)	$ -	0	$ -	0

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the carrying amounts used for income tax purposes. The components of deferred tax assets and liabilities are as follows (in thousands):

	As of December 31,	
	2019	2018
Deferred Tax Assets:		
Tax benefit of NOL carryforwards	$ 8,768	$ 7,012
Amortization of licenses	733	802
Other	98	7
Total deferred tax assets	9,599	7,821
Deferred tax liabilities	(8)	(7)
Net deferred tax assets	9,591	7,814
Valuation allowance for net deferred tax assets	(9,591)	(7,814)
Net deferred taxes	$ -	$ -

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which temporary differences become deductible. Due to the uncertainty of the Company's ability to realize the benefit of the deferred tax assets, the net deferred tax assets are fully offset by a valuation allowance at December 31, 2019 and 2018.

At December 31, 2019, the Company had federal net operating loss ("NOL") carryforwards, which are available to offset future federal taxable income. The Company had $41.8 million and $33.4 million of federal net operating tax loss carryforwards as of December 31, 2019 and 2018, respectively. NOL carryforwards generated before January 1, 2018 will fully expire by 2038 unless utilized. NOLs generated in 2018 and later years have unlimited carryforward with an 80% of taxable income limitation.

However, as a result of prior changes in the ownership of the Company's capital stock, the NOL carryforwards may be subject to certain limitations under Section 382 of the Internal Revenue Code of 1986, as amended ("IRC Sec. 382"). To date, the Company has not engaged tax advisors to conduct a study of potential limitations of the NOL carryforwards under IRC Sec. 382, resulting from prior changes in the ownership of the Company's capital stock. Accordingly, there can be no assurance as to the extent, if any, that the NOL carryforwards will be available to offset future federal taxable income of the Company.

For the years ended December 31, 2019 and 2018, no amounts have been recognized for uncertain tax positions and no amounts have been assessed or recognized related to interest or penalties related to uncertain tax positions. The Company has determined that it is not reasonably likely for the amounts of unrecognized tax benefits to significantly increase or decrease within the next twelve months. The Company is currently subject to the general three-year statute of limitation for federal tax. Under this general rule, the earliest period subject to potential audit is 2015. For years in which the company may utilize its net operating losses, the IRS may examine the tax year that generated the losses and propose adjustments up to the amount of losses utilized.

(11) Research and License Agreements

(a) Grants and Awards

The Company was the recipient of an award from the Therapeutics for Rare and Neglected Diseases ("TRND") program of the National Institutes of Health ("NIH"). In cooperation with the Company, TRND has been supporting ongoing nonclinical development of cyclocreatine as a therapeutic for Creatine Transporter Deficiency ("CTD"). The award is a Cooperative Research and Development Agreement ("CRADA") whereby NIH provides in-kind contribution with staff and facilities and is in effect through February 10, 2021.

(b) Development and License Agreements

(i) 2012 Settlement Agreement

The Company and certain executives and Board members were involved in litigation in the Federal District Court in Austin, Texas (the "Court"), with a former licensor, Avicena Group, Inc. ("Avicena") and its CEO from June 2011 until November 2012. The litigation was resolved by a binding settlement agreement (the "2012 Settlement Agreement") signed by the parties and an order of dismissal signed by the Court.

The 2012 Settlement Agreement imposes certain restrictions on the Company's right to develop or market therapies for use in connection with Parkinson's, Huntington's, ALS diseases, or skin care ailments, and its right to use creatine or its salts for any therapy, except CTD. The Company does not regard these restrictions as impediments to its ability to develop and market cyclocreatine as a drug therapy for CTD. In the 2012 Settlement Agreement, Avicena has agreed that for 25 years, it will not use, develop, or market cyclocreatine for any purpose.

(ii) University of Cincinnati License Agreement

In March 2012, the Company entered into a license agreement with the University of Cincinnati ("UC") (the "UC License Agreement"). Under the terms of the UC License Agreement, UC granted the Company an exclusive worldwide license to develop, manufacture, and commercialize therapeutics related to UC's licensed products.

Under the UC License Agreement, the Company paid UC an up-front fee of $50,000, which was recorded as research and development expense in 2014. The annual license fees increasing from $2,000 in first, second, and third anniversaries (2013–2015) to $15,000 in the fourth (2016) and $30,000 in the fifth anniversary (2017- 2018). The Company may be required to make future milestone payments contingent upon attainment of various development and regulatory approval milestones for the licensed product in any country. The milestone payments are payable in various amounts upon the start of different phases of clinical trials, application, and receipt of regulatory approval, with $50,000 upon completion of Phase II clinical study, $50,000 upon completion of Phase III clinical study, and $150,000 upon FDA approval of a new drug application for a licensed product. Additionally, upon commercial sales of the product, the Company will be required to pay to UC a royalty on net sales of the licensed products in any country or region, if such product sales are ever achieved. The running royalty ranges from 2.5%–3.5% of net sales and also contains provisions for sublicense fees.

This UC License Agreement was terminated on October 25, 2019 which included a mutual release of all claims under the UC License Agreement. No payments were required by Lumos in connection with the termination.

(iii) Merck License Agreement

In July 2018, the Company entered into an asset purchase agreement (the "APA") with Ammonett Pharma LLC ("Ammonett") to acquire assets of Ammonett which comprised primarily of its license with Merck Sharpe & Dohme Corp ("Merck License") as well as related patents, intellectual property and product inventory.

Under the APA, the Company paid Ammonett and upfront fee of $3,500,000 which was recorded as research and development expense in 2018, as further described in notes 2(i) and 3(d). The Company may also incur development milestone payments totaling up to $17 million for achievement of specified milestones on the first indication that Lumos pursues and up to $14 million for achievements of specified milestones on the second indication that Lumos pursues, sales milestone payments totaling up to $55 million on worldwide product sales, and royalty payments based on worldwide product sales, as discussed below.

In connection with the APA and assignment of the Merck License, 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 million are required on worldwide net product sales up to $1 billion, and substantial royalty payments based on product sales are required if product sales are achieved. If product sales are ever achieved, Lumos is required to make royalty payments under both the APA and the Merck License collectively of 10% to 12% of total annual product net sales, subject to standard reductions for generic erosion. The royalty obligations under the Merck License 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 Merck License 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 Merck License converts to a fully paid-up, perpetual non-exclusive license.

(iv) Vigilan Transfer Agreement

The Company had been conducting a natural history study ("Vigilan") in conjunction with the NIH and certain hospitals in the United States. Pursuant to a letter of agreement, Vigilan is being transferred to another biopharmaceutical company with an ongoing program to target related patients. Pursuant to the letter of agreement, the Company received $120,000 for reimbursement of Lumos personnel assistance during the transition period, as well as reimbursement of $247,000 of direct costs, which are shown as a reduction in R&D expense. The transition was completed prior to the end of 2019 and no further costs for such study will be incurred by the Company.

(12) Related-Party Transactions

Pursuant to the Employment Agreement between the Company and its CEO, if the CEO is terminated by the Company without cause or the CEO resigns with good reason, then the CEO is entitled to lump-sum payment as more fully set forth in the agreement.

If the Company offers additional shares of equity in transactions for which the primary purpose is to raise capital, the Company's CEO has a preemptive right to subscribe to his pro rata share of equity securities granted upon the same terms that is offered to others, per his employment agreement, dated January 24, 2014.

(13) Commitments and Contingencies

The Company indemnifies each of its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as an officer or a director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid.

(14) Merger Agreement

On September 30, 2019, the Company, NewLink Genetics Corporation ("NewLink"), and Cyclone Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of NewLink (the "Merger Sub"), entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub would merge with and into the Company, with the Company surviving as a wholly-owned subsidiary of NewLink (the "Merger"). The Merger was approved by a vote of NewLink stockholders in a special meeting held on March 17, 2020 and the Merger was consummated on March 18, 2020. Subsequent to this date, the former NewLink Genetics Corporation is now named Lumos Pharma, Inc.

Immediately following the Merger, former Company stockholders own approximately 50% of the aggregate number of shares of Lumos Pharma, Inc. common stock issued and outstanding following the consummation of the Merger (the "Post-Closing Stock"), and the stockholders of NewLink as of immediately prior to the Merger own approximately 50% of the aggregate number shares of Post-Closing Stock.

(15) Subsequent Events

In March 2020, the World Health Organization declared the outbreak of COVID-19, a novel strain of Coronavirus, a global pandemic. This outbreak is causing major disruptions to businesses and markets worldwide as the virus spreads. The extent of the effect on the Company's operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic, and governmental, regulatory and private sector responses, all of which are uncertain and difficult to predict. Although the Company is unable to estimate the financial effect of the pandemic at this time, if the pandemic continues to evolve into a severe worldwide crisis, it could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows. The financial statements do not reflect any adjustments as a result of the pandemic.

The Company evaluated subsequent events occurring after December 31, 2019 up to April 10, 2020 the date the financial statements were available to be issued.

Exhibit 99.3

Unaudited Pro Forma Combined Financial Information

On March 18, 2020, NewLink completed its transaction to merge (the "Merger") with Lumos in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of September 30, 2019, by and among NewLink, Cyclone Merger Sub, Inc., and Lumos. Pursuant to the Agreement and Plan of Merger, Cyclone Merger Sub, Inc. merged with and into Lumos, with Lumos surviving as a wholly-owned subsidiary of NewLink.

Immediately after the Merger, former Lumos stockholders own approximately 50% of the outstanding common stock of the combined company, with former NewLink stockholders also owning approximately 50% of the outstanding common stock of the combined company.

Also on March 18, 2020, and prior to the effective time of the Merger, NewLink effected a 1-for-9 reverse stock split of its common stock (the "Reverse Stock Split"). Following the Merger and the Reverse Stock Split, NewLink changed its name to "Lumos Pharma, Inc."

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

The unaudited pro forma condensed combined balance sheet as of December 31, 2019 assumes that the Merger took place on December 31, 2019 and combines the historical balance sheets of NewLink and Lumos as of December 31, 2019. The unaudited pro forma condensed combined statements of operations for the year ended December 31, 2019 assume that the Merger took place as of January 1, 2019 and combines the historical results of NewLink and Lumos for the year ended December 31, 2019, respectively. The historical financial statements of NewLink and Lumos, which are provided (or incorporated by reference) elsewhere in this Form 8-K/A, have been adjusted to give pro forma effect to events that are (i) directly attributable to the Merger, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results. Unless otherwise noted herein, all references to share amounts, including loss per share amounts, give effect to the Reverse Stock Split.

Exhibit 99.3

The unaudited pro forma condensed combined financial statements are based on the assumptions and adjustments that are described in the accompanying notes. The unaudited pro forma condensed combined financial statements and pro forma adjustments have been prepared based on preliminary estimates of fair value of assets acquired and liabilities assumed. Differences between these preliminary estimates and the final fair value of assets and liabilities acquired may occur and these differences could have a material impact on the accompanying unaudited pro forma combined financial statements and the combined company's future results of operations and financial position. The actual amounts recorded as of the completion of the Merger may differ materially from the information presented in these unaudited pro forma condensed combined financial statements as a result of the amount of cash used by NewLink's operations between the balance sheet date of December 31, 2019 and the closing of the Merger; the timing of the closing of the Merger; and other changes in NewLink's assets and liabilities that occur prior to the Merger.

The unaudited pro forma condensed combined financial statements do not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the acquisition. The unaudited pro forma condensed combined financial statements have been prepared for illustrative purposes only and are not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had NewLink and Lumos been a combined company during the specified period. The unaudited pro forma condensed combined financial statements, including the notes thereto, should be read in conjunction with the NewLink and Lumos historical audited financial statements for the years ended December 31, 2019 and 2018, respectively, which are included or incorporated by reference in this Form 8-K/A.

Exhibit 99.3

Unaudited Pro Forma Condensed Combined Balance Sheet

As of December 31, 2019

(in thousands, except per share information)

	NewLink Historical	Lumos Historical	Pro Forma Adjustments	Notes	Pro Forma Combined
Current assets					
Cash and cash equivalents	$ 90,549	$ 4,952	$ -		$ 95,501
Prepaid expenses and other current assets	3,046	117	-		3,163
Current income tax receivable	69	-	-		69
Other receivables	755	-	-		755
Total current assets	94,419	5,069	-		99,488
Non-current assets:					
Property and Equipment	9,423	238	(7,790)	D	1,871
Less accumulated depreciation and amortization	(7,790)	(154)	7,790	D	(154)
Property and Equipment, net	1,633	84	-		1,717
Right-of-use-asset	735	373	-		1,108
Economic interest in Priority Review Voucher (PRV)	-	-	87,920	D	87,920
Other Intangible assets	-	-	426	D	
	-	-	(426)	G	-
Total assets	$ 96,787	$ 5,526	$ 87,920		$ 190,233
Current liabilities					
Accounts payable	$ 475	$ 365	$ -		$ 840
Accrued expenses	10,198	709	1,827	E,F	12,734
Income taxes payable	11	-	-		11
PRV-related asset owed to Merck	-	-	35,720	D	35,720
Current portion of lease liability	1,100	189	-		1,289
Current portion of notes payable	43	-	-		43
Total current liabilities	11,827	1,263	37,547		50,637
Long-term liabilities					
Authority	6,000	-	-		6,000
Lease liability	82	191	-		273
Deferred tax liability	-	-	9,500	D	9,500
Total long-term liabilities	6,082	191	9,500		15,773
Total liabilities	17,909	1,454	47,047		66,410
Series B redeemable convertible preferred stock	-	41,631	(41,631)	A	-
Series A redeemable convertible preferred stock	-	21,904	(21,904)	A	-
Shareholders' equity					
Blank check preferred stock	-	-	-		-
Common Stock	374	1			
			30	A	
			(1)	B	
			12	B	
			(332)	K	84
Additional paid in capital	413,959	213			
			63,505	A	
			(11)	B	
			(334,001)	C	
			43,126	D	
			332	K	
			(1,454)	J	185,669
Treasury stock	(1,454)	-	1,454	J	-
Accumulated deficit	(334,001)	(59,677)			
			334,001	C	
			(1,641)	E	
			(186)	F	
			(426)	G	(61,930)
Total shareholders' equity	78,878	(59,463)	104,408		123,823
Total liabilities and shareholders' equity	96,787	(58,009)	151,455		190,233
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 96,787	$ 5,526	$ 87,920		$ 190,233

See accompanying notes to the Unaudited Pro Forma Condensed Combined Financial Information.

Exhibit 99.3

Unaudited Pro Forma Condensed Combined Statement of Operations

Year Ended December 31, 2019

(in thousands, except per share information)

	NewLink Historical	Lumos Historical	Pro Forma Adjustments	Notes	Pro Forma Combined
Operating Revenues:					
Grant revenue	$ -	$ -	$ -		$ -
Licensing revenue	936	-	-		936
Total revenue	936	-	-		936
Operating Expenses:					
Research and development expenses	22,205	5,669	-		27,874
General and administrative expenses	23,865	4,147	(3,671)	H	24,341
Total operating expenses	46,070	9,816	(3,671)		52,215
Loss from operations	(45,134)	(9,816)	3,671		(51,279)
Other income and expense:					
Miscellaneous expense	(19)	-	-		(19)
Interest income	2,226	111	-		2,337
Interest expense	(50)	-	-		(50)
Total other income, net	2,157	111	-		2,268
Net loss before taxes	(42,977)	(9,705)	3,671		(49,011)
Income tax expense	(12)	-	-		(12)
Net loss	$ (42,989)	$ (9,705)	$ 3,671		$ (49,023)
Basic and diluted loss per share	$ (10.37)	-	$ -		$ (5.83)
Basic and diluted average shares outstanding	4,143,834		4,270,206	I	8,414,040

See accompanying notes to the Unaudited Pro Forma Condensed Combined Financial Information.

Notes to Unaudited Pro Forma Condensed Combined Financial Information

(in thousands, except per share information)

Note 1 – Basis of Presentation

The unaudited pro forma condensed combined financial statements are based on Lumos' and NewLink's historical consolidated financial statements as adjusted to give effect to the reverse merger and the Reverse Stock Split. The unaudited pro forma condensed combined statements of operations for the year ended December 31, 2019 give effect to the Merger as if it had occurred on January 1, 2019. The unaudited pro forma condensed combined balance sheet as of December 31, 2019 gives effect to the Merger as if it had occurred on December 31, 2019. The historical financial information has been adjusted in the unaudited pro forma combined financial statements to give effect to pro forma events that are (i) directly attributable to the acquisition, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined company's results. The Merger was accounted for as an asset acquisition rather than a business combination because the operations acquired, and liabilities assumed by Lumos do not meet the definition of a business as defined by ASC 805, Business Combinations as NewLink does not contain the processes in place to generate outputs. The net assets to be acquired in connection with the Merger were recorded at their estimated acquisition date fair values as of December 31, 2019. Unless otherwise noted, all extra period to share amounts, including loss per share amounts, give effect to the Reverse Stock Split.

The pro forma adjustments described below were based on management's assumptions and estimates, including assumptions relating to the consideration paid and the allocation thereof to the assets acquired and liabilities assumed from NewLink based on preliminary estimates of fair value. The final purchase consideration and the allocation of the purchase consideration may differ from that reflected in the unaudited pro forma combined financial information after final valuation procedures are performed and amounts are finalized following the completion of the Merger.

The pro forma condensed combined financial statements do not necessarily reflect what the combined company's financial condition or results of operations would have been had the Merger occurred on the dates indicated. They also may not be useful in predicting the future financial condition and results of operations of the combined company. The actual financial position and results of operations may differ significantly from the pro forma amounts reflected herein due to a variety of factors.

The unaudited pro forma condensed combined financial information does not reflect any integration activities or cost savings from operating efficiencies, synergies, asset dispositions, or other restructurings that could result from the Merger.

Note 2 – Estimated Consideration and Preliminary Purchase Price Allocation

The estimated fair value of the net assets of NewLink on a pro forma basis on December 31, 2019, including the fair value of acquired intangible assets not previously reflected on NewLink's balance sheet, after giving effect of accruals of costs expected to be incurred in connection with the merger was $122.0 million. As NewLink's assets were predominately comprised of cash offset by current liabilities, the pro forma carrying value of NewLink's net assets is considered to be the best indicator of the fair value and, therefore, the preliminary estimated purchase price as of December 31, 2019. The estimated preliminary purchase price at the Merger closing date will change due to the amount of cash used by NewLink's operations after December 31, 2019 through the closing of the Merger on March 18, 2020 and other changes in the NewLink assets and liabilities that occur through the completion of the Merger. The preliminary purchase price assigned a value to the assets and liabilities acquired based on the accumulated cost of the acquisition and allocated based on the acquired assets and liabilities relative fair value. Given the cost of the acquisition was computed based on the fair value of the net assets acquired, the relative fair values assigned equate to the computed fair values of the acquired assets and liabilities.

The preliminary acquired net assets of NewLink based on their pro forma estimated fair values as of December 31, 2019 are as follows (in thousands):

Assets acquired:		
Cash and cash equivalents	$	90,549
Prepaid and other current assets		3,870
Property and equipment		1,633
Economic interest in Priority Review Voucher (PRV)		87,920
Other intangible assets		426
Other non-current assets		735
Total assets acquired		185,133
Liabilities assumed:		
Accounts payable		475
Accrued expenses and other current liabilities		11,352
PRV-related liability owed to Merck		35,720
Royalty obligation payable to Iowa Economic Development Auhority		6,000
Deferred tax liability		9,500
Other long-term liabilites		82
Total liabilities assumed		63,129
Total net assets acquired	$	122,004

The allocation of the estimated purchase price is preliminary because the determination of the fair values of assets acquired and liabilities assumed is not complete. The final determination of the purchase price allocation is anticipated to be completed as soon as practicable after completion of the Merger and will be based on the fair values of the assets acquired and liabilities assumed as of March 18, 2020, the closing date. The final amounts allocated to assets acquired and liabilities assumed could differ significantly from the amounts presented in the unaudited pro forma combined financial statements.

Note 3 – Unaudited Pro Forma Adjustments

A. To reflect the conversion of all Lumos preferred stock to NewLink common stock in connection with the Merger. The conversion ratios were set per the Merger Agreement and adjusted for the 9-to-1 reverse stock split. Lumos Series B redeemable convertible preferred stock was converted at a ratio of 1-for-0.199634 shares of common stock. Lumos Series A redeemable convertible preferred stock was converted at a ratio of 1-for-0.087362 shares of common stock.

B. To reflect the conversion of Lumos common stock to NewLink common stock in connection with the Merger, using the conversion ratio set per the Merger Agreement adjusted for the 9-to-1 reverse stock split, at a conversion ratio of 1-for-0.130831 shares of common stock.

C. To reflect the elimination of NewLink's historical accumulated deficit.

D. To reflect the fair values of the NewLink assets and liabilities acquired by Lumos. The fair value of the economic interest in priority review voucher (PRV) relates to the fair value expected to be received upon the monetization of the PRV. On January 3, 2020, Merck, NewLink's licensee, notified NewLink that the Federal Drug Administration (FDA) issued Merck a PRV relating to the approval of ERVEBO® (Ebola Zaire Vaccine, Live). Under the terms of the Merck Agreement, on February 4, 2020, Merck assigned all of its rights and interests in connection with the PRV to NewLink. NewLink is entitled to 60 percent of the value of the PRV obtained through sale, transfer or other disposition of the PRV, with 40 percent to be payable to Merck upon completion of the sale. NewLink intends to sell the PRV in the open market. NewLink does not intend to use the PRV for any purpose other than sale in the open market for cash consideration. Management computed the fair value using an estimated transaction price of $87.8 million, less expected taxes and fees. The 40 percent ownership owed to Merck is separately reflected as a liability in the pro forma condensed combined balance sheet. NewLink used an estimated transaction price of $87.8 million based on the mid-point of the range using the first and third quartile transaction values of six publicly disclosed transactions of $87.8 million to $107.5 million, respectively, since 2018. This reflects the most current observable inputs as of December 31, 2019 and trends in the market of PRVs and accounts for the decline in the transaction values since the peak sale of $350.0 million in 2015. The timing of the sale of the PRV may be impacted by the COVID-19 pandemic, however, for the valuation at December 31, 2019, no adjustments to timing were made. The fair values of the NewLink assets did not attribute any value to future royalties that NewLink might be entitled to receive under the Merck Agreement or from other assets because management did not believe that any such royalties would be paid in the foreseeable future, if ever.

   The deferred tax liability reflects the potential tax liability owed on the PRV, net of the amount owed to Merck, and adjusted for net operating loss carryforwards not limited by Section 382 limitations that NewLink anticipates it will be able to use against the income as of the Merger Date.

E. To record NewLink's estimated transaction costs, which include legal and advisory fees other transaction related fees that were not incurred as of December 31, 2019

F. To record Lumos's estimated transaction costs, which include legal and advisory fees other transaction related fees that were not incurred as of December 31, 2019

G. To record the research and development costs for the in-process research and development acquired from NewLink that has no future alternative use.

H. To reflect elimination of transaction costs, which include legal and advisory fees and other transaction related fees that were incurred for the year ending December 31, 2019.

I. Adjustment reflects the 4,270,206 additional shares of NewLink common stock issued as part of the Merger at the exchange ratios defined within the agreement adjusted for the Lumos weighted average number of shares of common stock outstanding during the period adjusted based on the exchange ratios for NewLink common stock. As the combined company is in a net loss position, any adjustment for potentially dilutive shares would be anti-dilutive, and as such basic and diluted loss per share are the same. NewLink's historical loss per share of $1.15 as of December 31, 2019 was based on basic and diluted average shares outstanding of 37,294,505. After giving effect of the 1-for-9 reverse stock split, NewLink's historical loss per share was $10.37 and basic and diluted average shares outstanding was 4,143,834.

The tables below reflect the pro forma adjustments (in thousands, except share and per share data):

The tables below reflect the pro forma adjustments (in thousands, except share and per share data):

	Pro Forma Year Ended December 31, 2019
Pro forma net loss	$ (49,023)
Basic and diluted net loss per share	(5.83)
Basic and diluted weighted average shares outstanding	8,414,040

The calculation of pro forma basic and diluted weighted average shares is as follows:

	Pro Forma Year Ended December 31, 2019
Basic and diluted weighted average shares:	
NewLink historical weighted average shares outstanding	4,143,834
Lumos historical weighted average number of shares outstanding, converted using defined exchange ratios	4,270,206
Pro forma basic and diluted weighted average shares outstanding	8,414,040

J. To reflect the elimination of 12,778 shares of NewLink treasury stock and 1,350,000 shares of Lumos treasury stock that were cancelled in connection with the merger.

K. To reflect the Reverse Stock Split on NewLink common shares outstanding.