UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

☒ Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
For the quarterly period ended June 30, 2020.
☐ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
For the transition period from to .
Commission File Number
001-35342

LUMOS PHARMA, INC.

(Exact name of Registrant as specified in Its Charter)

Delaware	**42-1491350**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4200 Marathon Blvd #200
Austin, Texas 78756
(512) 215-2630
(Address, including zip code, and telephone number, including area code, of principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	LUMO	The Nasdaq Stock Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

As of August 13, 2020, there were 8,293,312 shares of the registrant’s Common Stock, par value $0.01 per share, outstanding.

Lumos Pharma, Inc.

FORM 10-Q

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PART I

Lumos Pharma, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share data)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 72,697	$ 4,952
Prepaid expenses and other current assets	5,158	82
Income tax receivable	4,666	—
Other receivables	296	35
Economic interest in Priority Review Voucher ("PRV"), held for sale	87,920	—
Total current assets	170,737	5,069
Non-current assets:		
Property and equipment, net	834	84
Right-of-use asset	627	373
Total non-current assets	1,461	457
Total assets	$ 172,198	$ 5,526
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 155	$ 365
Accrued expenses	5,944	709
Current portion of lease liability	731	189
Current portion of notes payable	11	—
PRV related liability, held for sale	35,720	—
Total current liabilities	42,561	1,263
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	—
Lease liability	88	191
Deferred tax liability	7,084	—
Total long-term liabilities	13,172	191
Total liabilities	55,733	1,454
Commitments and contingencies		
Redeemable convertible preferred stock:		
Series A redeemable convertible preferred stock, $0.0001 par value: Authorized, issued and outstanding shares - 0 and 978,849 at June 30, 2020 and December 31, 2019, respectively	—	21,904
Series B redeemable convertible preferred stock, $0.0001 par value: Authorized, issued and outstanding shares - 0 and 1,989,616 at June 30, 2020 and December 31, 2019, respectively	—	41,631
Stockholders' equity (deficit):		
Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at June 30, 2020 and December 31, 2019, respectively: issued and outstanding shares - 0 at June 30, 2020 and December 31, 2019	—	—
Common stock, $0.01 par value: Authorized shares - 75,000,000 and 36,000,000 at June 30, 2020 and December 31, 2019, respectively; issued and outstanding 8,293,312 and 1,177,933 at June 30, 2020 and December 31, 2019, respectively	83	12
Additional paid-in capital	181,723	202
Accumulated deficit	(65,341)	(59,677)
Total stockholders' equity (deficit)	116,465	(59,463)
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 172,198	$ 5,526

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Licensing and collaboration revenue	$ 33	$ —	$ 55	$ —
Total revenues	33	—	55	—
Operating expenses:				
Research and development	2,763	1,881	4,669	3,336
General and administrative	4,147	714	7,478	1,397
Total operating expenses	6,910	2,595	12,147	4,733
Loss from operations	(6,877)	(2,595)	(12,092)	(4,733)
Other income and expense:				
Miscellaneous income, net	24	26	161	59
Interest income	74	—	79	—
Interest expense	—	—	(50)	—
Other income, net	98	26	190	59
Net loss before taxes	(6,779)	(2,569)	(11,902)	(4,674)
Income tax benefit	1,426	—	6,889	—
Net loss	$ (5,353)	$ (2,569)	$ (5,013)	$ (4,674)
Accretion of preferred stock to current redemption value	—	(758)	(651)	(1,508)
Net loss attributable to common shareholders	$ (5,353)	$ (3,327)	$ (5,664)	$ (6,182)
Basic and diluted loss per share	$ (0.65)	$ (2.47)	$ (1.08)	$ (4.59)
Basic and diluted average shares outstanding	8,292,809	1,345,402	5,243,577	1,345,402

See accompanying notes to condensed consolidated financial statements.

Lumos Pharma, Inc.
Condensed Consolidated Statement of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)
(In thousands, except share data)

Three and Six Month Periods ended June 30, 2020

	Series A redeemable convertible preferred stock		Series B redeemable convertible preferred stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	978,849	$ 21,904	1,989,616	$ 41,631	1,177,933	$ 12	$ 202	$ (59,677)	$ (59,463)
Accretion of preferred stock to current redemption value (pre-merger)	—	216	—	435	—	—	—	(651)	(651)
Issuance of common stock to former stockholders of NewLink upon merger	—	—	—	—	4,146,405	41	116,908	—	116,949
Conversion of preferred stock into common stock upon merger	(978,849)	(22,120)	(1,989,616)	(42,066)	2,968,465	30	64,156	—	64,186
Share-based compensation	—	—	—	—	—	—	177	—	177
Net income	—	—	—	—	—	—	—	340	340
Balance at March 31, 2020	—	$ —	—	$ —	8,292,803	$ 83	$ 181,443	$ (59,988)	$ 121,538
Share-based compensation	—	—	—	—	—	—	274	—	274
Sales of shares under stock purchase plan	—	—	—	—	509	—	6	—	6
Net loss	—	—	—	—	—	—	—	(5,353)	(5,353)
Balance at June 30, 2020	—	$ —	—	$ —	8,293,312	$ 83	$ 181,723	$ (65,341)	$ 116,465

Three and Six Month Periods ended June 30, 2019

	Series A redeemable convertible preferred stock		Series B redeemable convertible preferred stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	978,849	$ 20,903	1,989,616	$ 39,592	1,345,402	$ 1	$ 12	$ (46,932)	$ (46,919)
Share-based compensation	—	—	—	—	—	—	48	—	48
Accretion of preferred stock to current redemption value (pre-merger)	—	247	—	503	—	—	—	(750)	(750)
Net loss	—	—	—	—	—	—	—	(2,105)	(2,105)
Balance at March 31, 2019	978,849	$ 21,150	1,989,616	$ 40,095	1,345,402	$ 1	$ 60	$ (49,787)	$ (49,726)
Share-based compensation	—	—	—	—	—	—	40	—	40
Accretion of preferred stock to current redemption value	—	250	—	508	—	—	—	(758)	(758)
Net loss	—	—	—	—	—	—	—	(2,569)	(2,569)
Balance at June 30, 2019	978,849	$ 21,400	1,989,616	$ 40,603	1,345,402	$ 1	$ 100	$ (53,114)	$ (53,013)

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2020	**2019**
Cash Flows From Operating Activities		
Net loss	$ (5,013)	$ (4,674)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	451	88
Depreciation and amortization	313	16
Impairment of right-of-use (ROU) asset	(29)	—
Amortization of ROU asset and change in operating lease liability	(93)	4
In-process research and development charge	426	—
Benefit for deferred taxes	(2,416)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,423)	(8)
Other receivables	85	—
Accounts payable and accrued expenses	(3,237)	103
Income taxes receivable	(4,474)	—
Net cash used in operating activities	(16,410)	(4,471)
Cash Flows From Investing Activities		
Cash acquired in connection with merger	84,179	—
Purchase of equipment	(14)	—
Net cash provided by investing activities	84,165	—
Cash Flows From Financing Activities		
Sales of shares under stock purchase plan	6	—
Principal payments on notes payable	(16)	—
Net cash used in financing activities	(10)	—
Net increase (decrease) in cash and cash equivalents	67,745	(4,471)
Cash and cash equivalents at beginning of period	4,952	14,022
Cash and cash equivalents at end of period	$ 72,697	$ 9,551

See accompanying notes to condensed consolidated financial statements.

Lumos Pharma, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Organization and Description of Business

Description of Business

Lumos Pharma, Inc. ("Lumos" or the "Company") is a clinical-stage biopharmaceutical company focused on the identification, acquisition, in-license, development, and commercialization of novel products for the treatment of rare diseases. The Company's 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.

Lumos and its subsidiaries have historically devoted substantially all of their efforts toward research and development. The Company has never earned revenue from commercial sales of its drugs.

The Company believes that its existing cash and cash equivalents as of June 30, 2020 are sufficient to satisfy its operating cash and needs to support the Company through read out of the Phase 2b clinical trial for its LUM-201 product candidate and at least one year after the filing of the Quarterly Report on Form 10-Q in which these financial statements are included. If available liquidity becomes insufficient to meet the Company's operating obligations as they come due, the Company's plans include selling additional shares of common stock, alternative funding arrangements and/or reducing expenditures as necessary to meet the Company's cash requirements. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity. Failure by the Company to successfully execute its plans or otherwise address its liquidity needs may have a material adverse effect on its business and financial position and may materially affect the Company's ability to continue as a going concern.

In March 2020, the World Health Organization declared the outbreak of COVID-19, a novel strain of Coronavirus, a global pandemic. In response to the COVID-19 pandemic, "shelter in place" orders and other public health guidance measures have been implemented across much of the United States, including in the locations of our offices, clinical trial sites, key vendors, and partners. 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.

Merger with NewLink Genetics Corporation

On March 18, 2020, Lumos, the company formerly known as NewLink Genetics Corporation ("NewLink"), completed a merger in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of September 30, 2019, by and among the Company, Cyclone Merger Sub, Inc. ("Merger Sub"), and what was then known as Lumos Pharma, Inc., which has since been renamed "Lumos Pharma Sub, Inc." ("Private Lumos") (as amended, the "Merger Agreement"), pursuant to which Merger Sub merged with and into Private Lumos, with Private Lumos surviving as a wholly-owned subsidiary of NewLink (the "Merger").

On March 18, 2020, and prior to the effective time of the Merger (the "Effective Time"), NewLink effected a 1-for-9 reverse stock split of its common stock (the "Reverse Stock Split") and, following the Merger, changed its name to "Lumos Pharma, Inc." Unless otherwise noted herein, all references to share amounts give effect to the Reverse Stock Split. Following the completion of the Merger, the business being conducted by the Company became primarily the business conducted by Private Lumos, which is a biopharmaceutical company focused on the identification, acquisition, in-license, development, and commercialization of novel products for the treatment of rare diseases.

Immediately following the Reverse Stock Split and the completion of the Merger, there were 8,292,803 shares of the Company's common stock outstanding. Under the terms of the Merger, Private Lumos stockholders received an aggregate of 4,146,398 shares of our 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 our 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 our 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. NewLink's shares of common stock listed on The Nasdaq Global Market, previously trading through the close of business on Wednesday, March 18, 2020 (the "Merger Date") under the ticker symbol "NLNK", commenced trading on The Nasdaq Global Market, under the ticker symbol "LUMO", on Thursday, March 19, 2020. The accompanying condensed consolidated financial statements and notes give retroactive effect to the exchange ratio and change in par value for all periods presented.

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

As such, the results of operations and cash flows prior to the Merger Date, relate to Private Lumos. Subsequent to the Merger Date the information in these unaudited financial statements relates to the Company and its consolidated entities. All share and per share amounts in the financial statements and related notes have been retroactively adjusted, where applicable, for all periods presented to give effect to the exchange ratio applied in connection with the Merger and the Reverse Stock Split.

2. Basis of Presentation

Basis of presentation

The accompanying unaudited interim consolidated financial statements include the accounts of the Company and its subsidiaries and all intercompany amounts have been eliminated. The unaudited interim consolidated financial statements have been prepared and presented by the Company in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC"), and, in management’s opinion, reflect all adjustments necessary to present fairly the Company’s interim condensed financial information.

Certain information and footnote disclosures normally included in the Company’s annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2019, included in NewLink's Annual Report on Form 10-K and the Company's Current Report on Form 8-K/A, filed with the SEC on May 29, 2020. The financial results for any interim period are not necessarily indicative of financial results for the full year.

The Company’s historical results are not necessarily indicative of the results to be expected in the future and the Company’s operating results for the three and six months ended June 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020.

The balance sheet at December 31, 2019 was derived from audited financial statements, but does not include all disclosure required by U.S. GAAP.

3. NewLink Genetics Merger

As described in Note 1, Private Lumos merged with the Company on March 18, 2020. The Merger was accounted for as a reverse merger with Private Lumos as the accounting acquirer based upon the terms of the Merger Agreement and other factors including: (i) Lumos stockholders owned approximately 50% of outstanding common stock of the Company immediately following the closing of the Merger, (ii) the board of directors of the Company (the "Board") consists of three members designated by the NewLink, three members designated by Private Lumos and the Board unanimously appointed a seventh member and (iii) the Company is led by Private Lumos’ then current chief executive officer and chief scientific officer, with other current members of senior management from both Private Lumos and NewLink. The Merger was accounted for as an asset acquisition in accordance with U.S. GAAP as the assets acquired and liabilities assumed from NewLink do not meet the definition of a business as defined by ASC 805, *Business Combinations* as NewLink did not contain the processes in place to generate outputs. For accounting purposes, Private Lumos acquired the assets and liabilities of NewLink in this Merger.

Lumos Pharma, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Management allocated the net assets acquired and liabilities assumed in connection with the transaction based on their estimated acquisition date fair values as described below.

The fair value of the net assets acquired on March 18, 2020 was $116.9 million. As NewLink's assets were predominately comprised of cash offset by current liabilities, the carrying value of NewLink's net assets, including the fair value of acquired intangible assets not previously reflected on NewLink's balance sheet, is considered to be the best indicator of the fair value and the purchase price. The 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 acquired net assets of NewLink based on their fair values as of March 18, 2020 are as follows (in thousands):

Assets acquired:		
Cash and cash equivalents	$	84,179
Prepaid and other current assets		2,999
Income tax receivable		192
Property and equipment		1,020
Economic interest in PRV		87,920
Other intangible assets		426
Other non-current assets		517
Total Assets Acquired		177,253
Liabilities assumed:		
Accounts payable		285
Accrued expenses and other current liabilities		8,788
PRV-related liability owed to Merck		35,720
Royalty obligation payable to Iowa Economics Development Authority		6,000
Deferred tax liability		9,500
Other long-term liabilities		12
Total liabilities assumed		60,305
Total net assets acquired	$	116,948

On January 3, 2020, Merck Sharp & Dohme Corp. ("Merck") notified NewLink that they had been issued a Priority Review Voucher ("PRV") in connection with the U.S. Food and Drug Administration (the "FDA") approval of ERVEBO® (Ebola Zaire Vaccine, Live). Under the terms of the NewLink Merck Agreement (as defined below), on February 4, 2020, Merck assigned all of its rights and interests in connection with the PRV to NewLink. The Company 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. Management used the precedent transaction method under the market approach to estimate the value of the PRV and relied on purchase prices indicated by actual precedent priority review voucher transactions that were reasonably comparable to the PRV owned by the Company. The market approach requires several judgments and assumptions to determine the fair value including discount rates, probability assumption of sale, expected consolidated transaction sales price, and tax rates. The 40 percent ownership owed to Merck is separately reflected as a liability in the condensed consolidated balance sheet. Management used an estimated transaction price of $95.0 million based on the observed median guideline transaction of the range of publicly disclosed transactions of $80.0 million to $111.0 million from 2018 and through 2020. This

reflected the most current observable inputs as of March 18, 2020 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 fair value assigned to the acquired in-process research and development assets was estimated based on the estimated expected net proceeds from the sales of these assets as intellectual property. These assets are no longer being actively pursued in further clinical development by the Company. The acquired in-process research and development expenses of $426,000 were expensed to research and development expenses in the statement of operations for the three months ended March 31, 2020.

4. Significant Accounting Policies

Risks and Uncertainties

The Company is monitoring the potential impact of COVID-19, if any, on the carrying value of certain assets and its continued operations. To date, the Company has not experienced material business disruption, nor has it incurred impairment of any assets as a result of COVID-19. The extent to which these events may impact the Company's business, clinical development and regulatory efforts, and the value of its common stock, will depend on future developments, which are highly uncertain and cannot be predicted at this time. The duration and intensity of these impacts and resulting disruption to the Company's operations is uncertain and the Company will continue to assess for any future potential financial impact, if any.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The condensed consolidated financial statements include the financial statements of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Financial Instruments and Concentrations of Credit Risk

Cash and cash equivalents, receivables, and accounts payable are recorded at cost, which approximates fair value based on the short-term nature of these financial instruments. The Company is unable to estimate the fair value of the royalty obligation based on future product sales, as the timing of payments, if any, is uncertain.

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, the Company's cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, the Company invests its excess cash primarily in high quality securities such as money market funds.

Share-Based Compensation

The Company is required to estimate the grant-date fair value of share-based payment transactions with employees which include stock options, restricted stock units ("RSUs") and performance shares and recognizes the compensation cost over the requisite service period based on the estimated fair values. The Company estimates the fair value of each award granted using the Black-Scholes option pricing model. The Black-Scholes model requires the input of assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs. The Company calculates the fair value of the award on the grant date, which is the date the award is authorized by the Board or by the Chief Executive Officer as delegated by the Board.

The Company has issued awards to nonemployee consultants and advisers. All grants to nonemployees are valued using the same fair value method that we use for grants to employees. The compensation cost on these awards is measured each period until vesting and is recognized through the earlier of the vesting of the award or completion of services by the nonemployee.

Following is a description of the inputs for the Black-Scholes model:

Exercise Price

The Company uses the quoted market price as listed on the public exchange on the date of grant. If incentive stock options are granted to a 10% stockholder in the Company, the exercise price shall not be less than 110% of the common stock's fair market value on the date of grant.

Expected Term

The expected term of a stock option is the period of time for which the option is expected to be outstanding. Due to the lack of historical exercise data to provide a reasonable basis upon which to estimate an expected term, we have opted to use the simplified method, which is the use of the midpoint of the vesting term and the contractual term of the award to estimate the expected term.

Risk-Free Interest Rate

The Company uses the average yield on current U.S. Treasury instruments with terms that approximate the expected term of the stock options being valued.

Expected Dividend Yield

The expected dividend yield for all of the Company's stock option grants is 0%, as the Company has not declared a cash dividend since inception and has no plans to declare a dividend.

Expected Volatility

As the Company does not have sufficient historical stock price information to meet the expected life of the stock option grants, it uses a blended volatility based on the trading history from the common stock of a set of comparable publicly-traded biopharmaceutical companies.

Forfeitures

The Company accounts for forfeitures as they occur.

Property and Equipment

Property and equipment are capitalized as the Company believes they have alternative future uses and are stated at cost, less accumulated depreciation of $403,000 and $154,000 as of June 30, 2020 and December 31, 2019, respectively. Depreciation on all property and equipment is calculated on the straight-line method over the shorter of the lease term or estimated useful life of the asset. Computer equipment has useful lives of three to five years, lab equipment has a useful life of five years, and contract manufacturing organization equipment has a useful life of five years.

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*. During the six months ended June 30, 2020, the Company expensed the in-process research and development asset of $426,000 acquired as part of the Merger as there is no future economic benefit. The expense of $426,000 is recorded within research and development costs within the consolidated statement of operations.

Asset Held for Sale

An asset is considered to be held for sale when all of the following criteria are met: (i) management commits to a plan to sell the asset; (ii) it is unlikely that the disposal plan will be significantly modified or discontinued; (iii) the asset is available for immediate sale in its present condition; (iv) actions required to complete the sale of the asset have been initiated; (v) sale of the asset is probable and the completed sale is expected to occur within one year; and (vi) the asset is actively being marketed for sale at a price that is reasonable given its current market value.

A long-lived asset classified as held for sale is measured at the lower of its carrying amount or fair value less cost to sell. If the long-lived asset is newly acquired, the carrying amount of the long-lived asset is established based on its fair value less cost to sell at the acquisition date. A long-lived asset is not depreciated or amortized while it is classified as held for sale, and an impairment loss would be recognized to the extent the carrying amount exceeds the asset's fair value less cost to sell.

Lumos has classified the PRV as held for sale and is carried at its original fair value less cost to sell on the condensed consolidated balance sheet as of June 30, 2020.

5. License and Research Collaboration Agreement

Merck Sharp & Dohme Corp.

In November 2014, NewLink entered into a licensing and collaboration agreement (the "NewLink Merck Agreement") with Merck to develop, manufacture and commercialize rVSV-ZEBOV-GP, an Ebola vaccine that NewLink licensed from the Public Health Agency of Canada ("PHAC"). Under the terms of the NewLink Merck Agreement, NewLink granted Merck an exclusive, royalty bearing license to rVSV-ZEBOV-GP and related technology. Under the NewLink Merck Agreement, NewLink received a $30.0 million non-refundable, upfront payment in December 2014, and a one-time $20.0 million non-refundable milestone payment in February 2015 upon the initiation of the pivotal clinical trial using the current rVSV-ZEBOV-GP vaccine product as one arm of the trial.

The NewLink Merck Agreement was amended on December 5, 2017 in connection with our entry into an amended and restated PHAC license on December 5, 2017. The amended NewLink Merck Agreement absolves our subsidiary, BioProtection Systems Corporation ("BPS"), from any future obligation to negotiate or amend the terms of the PHAC license, converts the scope of Merck's sublicense under PHAC’s intellectual property rights to be non-exclusive in the Ebola Sudan field of use, and requires Merck to reimburse us in certain circumstances where we may be obligated to pay royalties to PHAC as a result of Merck’s product sales but Merck would not otherwise be obligated to pay a royalty to us. On April 26, 2018, NewLink entered into an agreement with Merck, the U.S. BioMedical Advanced Research and Development Authority ("BARDA"), and the Defense Threat Reduction Agency ("DTRA") to transfer the government grants from BARDA and DTRA to Merck. The transfer was completed in June 2018 and Merck replaced NewLink as the prime contractor on all such grants.

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. 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. On July 27, 2020, the Company entered into the PRV Transfer Agreement to sell the PRV to Merck. The Company and Merck agreed to value the PRV at $100.0 million, of which the Company will receive 60% or $60.0 million in gross proceeds. The purchase price will be paid in two installments: $34.0 million will be paid upon closing of the sale and $26.0 million will be paid on January 11, 2021.

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

For the three and six months ended June 30, 2020, the Company recognized revenues under the amended NewLink Merck Agreement of $33,000, and $55,000, respectively, for work the Company performed as a subcontractor of Merck under the government contracts that were transferred to Merck.

6. Common Stock Equity Incentive Plans

Contemporaneous with the Merger closing, the Company assumed Private Lumos' 2012 Equity Incentive Plan and 2016 Equity Incentive Plan. Under these plans, the Company assumed 26,248 stock options issued and outstanding under the Private Lumos 2012 Equity Incentive Plan, with a weighted-average exercise price of $1.39 per share and 163,864 stock options issued and outstanding under the Private Lumos 2016 Stock Plan with a weighted-average exercise price of $3.66 per share. From and after the Effective Time, such options may be exercised for shares of our common stock under the terms of the respective plans under which they were granted.

2019 Equity Incentive Plan

In July 2009, the NewLink stockholders approved the 2009 Equity Incentive Plan (the “2009 Plan”), and in May 2019, NewLink's stockholders approved a proposal to amend and extend the 2009 Plan (the "2019 Plan") which remained in effect for the Company upon the Merger. Following the approval of the 2019 Plan, no additional stock awards will be granted under the 2009 Plan. Shares that remained available for issuance pursuant to the exercise of options or issuance or settlement of stock awards under the 2009 Plan became available for issuance pursuant to the 2019 Plan and all shares that would have otherwise returned to the 2009 Plan became available for issuance pursuant to the 2019 Plan. Under the provisions of the 2019 Plan, the Company may grant the following types of common stock awards:

- Incentive Stock Options
- Nonstatutory Stock Options
- Restricted Stock Awards
- Stock Appreciation Rights

Awards under the 2019 Plan, as amended, may be made to officers, employees, members of the Board, advisors, and consultants to the Company.

As of June 30, 2020, including the shares from the Private Lumos 2012 and 2016 Equity Incentive Plans that were assumed through the Merger, there were 1,692,379 shares of common stock authorized for issuance under our equity incentive plans, and 422,536 shares remained available for issuance under the 2019 Plan.

The increases in the authorized shares of common stock under the 2009 Plan in 2010 and 2011 were approved by NewLink's stockholders. The increases in the authorized shares of common stock under the 2009 Plan in 2012 through 2019 were made pursuant to an “evergreen provision,” in accordance with which, on January 1 of each year, from 2013 to (and including) 2019, a number of shares of common stock in an amount equal to 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or such lesser amount of shares (or no shares) approved by the Board, was added or will be added to the shares reserved under the 2009 Plan.

On May 9, 2019, NewLink's stockholders approved an amendment to the 2009 Plan which, among other modifications, included decreasing the automatic annual “evergreen provision” from 4% to 3%, in accordance with which, on January 1 of each year, from 2020 to (and including) 2029, a number of shares of common stock in an amount equal to 3% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or such lesser amount of shares (or no shares) approved by the Board, was added or will be added to the shares reserved under the 2019 Plan.

2010 Non-Employee Directors' Stock Award Plan

Under the terms of the Company’s 2010 Non-Employee Directors’ Stock Award Plan (the "Directors’ Plan") which became effective on November 10, 2011 and remains in effect upon the Merger, 26,455 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 17,989 shares of common stock were added to the shares reserved for future issuance under the Directors' Plan. As of June 30, 2020, no shares remain available for issuance under the Directors' Plan.

2010 Employee Stock Purchase Plan

Under the terms of the Company's 2010 Employee Stock Purchase Plan (the "2010 Purchase Plan"), which became effective for NewLink on November 10, 2011 and remains in effect upon the Merger, 23,809 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 20,635 shares of common stock were added to the shares reserved for future issuance under the 2010 Purchase Plan. As of June 30, 2020, 2,119 shares remained available for issuance under the 2010 Purchase Plan.

Share-Based Compensation

Share-based compensation expense for the three months ended June 30, 2020 and 2019 was $274,000 and $40,000, respectively. For the six months ended June 30, 2020 and 2019, share-based compensation was $451,000 and $88,000, respectively. Share-based compensation expense is allocated between research and development and general and administrative expenses within the condensed consolidated statements of operations.

As of June 30, 2020, the total compensation cost related to nonvested option awards not yet recognized was $3.4 million and the weighted-average period over which it is expected to be recognized is 3.5 years.

Stock Options and Performance Stock Options

The following table summarizes the stock option activity, including options with market and performance conditions and options granted and forfeited from December 31, 2019 through June 30, 2020:

	Number of options		Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	596,312	$	30.76	5.0
Options granted	504,104		8.09	
Options exercised	—		—	
Options forfeited	(2,011)		21.04	
Options expired	(29,426)		54.22	
Outstanding at end of period	1,068,979	$	19.44	7.2
Options exercisable at end of period	433,796	$	32.90	4.6

The Company estimates the fair value of each stock option grant on the date of grant using a Black-Scholes option pricing model. In conjunction with the Merger, the Company re-valued the outstanding awards under its equity incentive plans which did not result in a material incremental expense during the six months ended June 30, 2020.

The following table summarizes the range of assumptions used to estimate the fair value of stock options granted, including those options granted with a market condition, during the six months ended June 30, 2020:

Risk-free interest rate	0.42% to 0.46%
Expected dividend yield	—%
Expected volatility	86.1% to 88.7%
Expected term (in years)	5.8 to 6.1
Weighted-average grant-date fair value per share	$5.79

No options were exercised during the six months ended June 30, 2020. The fair value of awards vested during the six months ended June 30, 2020 was $687,000.

Restricted Stock and Performance Restricted Stock

Restricted stock is common stock that is subject to restrictions, including risks of forfeiture, determined by a committee of the Board in its sole discretion, for as long as such common stock remains subject to any such restrictions. A holder of restricted stock has all rights of a stockholder with respect to such stock, including the right to vote and to receive dividends thereon, except as otherwise provided in the award agreement relating to such award. Restricted stock awards are classified as equity within the consolidated balance sheets. The fair value of each restricted stock grant is estimated on the date of grant using the closing price of the Company's common stock on The Nasdaq Stock Market on the date of grant.

A summary of the Company's unvested restricted stock, including restricted stock with performance conditions, at June 30, 2020 and changes during the six months ended June 30, 2020 are as follows:

	Number of restricted shares	Weighted average grant date fair value
Unvested at beginning of period	210	$ 312.94
Granted	73,987	7.90
Vested	(443)	159.10
Forfeited/cancelled	—	—
Unvested at end of period	73,754	$ 7.86

The Company does not have a formal policy regarding the source of shares issued upon exercise of stock options or issuance of restricted stock. The Company expects shares issued to be issued from treasury shares or new shares.

7. Leases

The Company has certain facility leases with non-cancellable terms ranging between one and two years, with certain renewal options.

The Company records lease liabilities based on the present value of lease payments over the lease term using an incremental borrowing rate to discount its lease liabilities, as the rate implicit in the lease is typically not readily determinable. To compute the present value of the lease liability, the Company used a weighted-average discount rate of 5%. Certain lease agreements include renewal options that are under the Company's control. The Company includes optional renewal periods in the lease term only when it is reasonably certain that the Company will exercise its option. Prior to the Merger, NewLink had asserted it would not renew the lease terms through expiry of the lease renewal option periods. The weighted-average remaining lease term as of June 30, 2020 is less than 1.0 year.

The Company does not separate lease components from non-lease components. Variable lease payments include payments to lessors for taxes, maintenance, insurance and other operating costs as well as payments that are adjusted based on an index or rate. The Company's lease agreements do not contain any residual value guarantees or restrictive covenants.

Future minimum lease payments under the non-cancellable operating leases (with initial or remaining lease terms in excess of one year) as of June 30, 2020 are as follows (in thousands), excluding option renewals:

For the Year Ended December 31:	
2020	$ 376
2021	278
Total future minimum lease payments	654
Less: Imputed interest	(17)
Unamortized lease incentive	182
Total	$ 819

Lumos Pharma, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

8. Income Taxes

For the three and six months ended June 30, 2020, the Company recorded a benefit of $1.4 million and $6.9 million, respectively. For the three and six months ended June 30, 2019, the Company recorded no income tax benefit. The income tax benefit is show below (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Current tax benefit	$ —	$ —	$ 4,473	$ —
Deferred tax benefit	1,426	—	2,416	—
Total income tax benefit	$ 1,426	$ —	$ 6,889	$ —

On March 25, 2020, in response to the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) was signed into law to provide emergency assistance to affected individuals, families, and businesses. The CARES Act provides numerous tax provisions and other stimulus measures, including temporary changes regarding the prior and future utilization of net operating losses. The CARES Act amends the net operating losses ("NOLs") provisions of the Tax Cut and Jobs Act of 2017 (the "Tax Act"), providing for a five year carryback for NOLs generated in tax years beginning after December 31, 2017 and before January 1, 2021. A tax benefit of $4.5 million related to pre-tax NOLs was carried back to each of the five taxable years to fully offset taxable income with a full receivable recorded for this amount as of June 30, 2020. The Company received the full refund in July 2020.

The income tax amount for the three and six months ended June 30, 2020 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to the benefit of $4.5 million recorded as a result of the CARES Act. Additionally, the income tax benefit for the three and six months ended June 30, 2020 includes $1.4 million and $2.4 million, respectively, for the release of the valuation allowance related to Private Lumos NOLs and a current period benefit for losses the Company anticipates will be offset by future income. The income tax amount for the three and six months ended June 30, 2019 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to the full valuation allowance.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. As a result of the Merger, a deferred tax liability of $9.5 million was recorded for the step up in book basis over tax basis for the net value of the PRV which the Company sold in July 2020. A net deferred tax liability of $7.1 million is shown on the condensed consolidated balance sheet as of June 30, 2020. As of June 30, 2020, there is not a valuation allowance recorded.

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

The Company has a reserve for uncertain tax positions related to state tax matters of $653,000 as of June 30, 2020 recorded within accrued expenses in the condensed consolidated balance sheet, which includes the accrual of interest and penalties. The Company does not expect the amount to change significantly within the next 12 months.

9. Net Loss per Share of Common Stock

Basic loss per share is based upon the weighted-average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. Diluted loss per share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average potentially dilutive common stock equivalents during the period when the effect is dilutive.

The following table presents the computation of basic and diluted loss per share of common stock (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	$ (5,353)	$ (2,569)	$ (5,013)	$ (4,674)
Accretion of preferred stock to current redemption value	—	(758)	(651)	(1,508)
Net loss attributable to common shareholders	$ (5,353)	$ (3,327)	$ (5,664)	$ (6,182)
Basic and diluted weighted-average shares outstanding	8,292,809	1,345,402	5,243,577	1,345,402
Basic and diluted loss per share	$ (0.65)	$ (2.47)	$ (1.08)	$ (4.59)

All common stock equivalents are excluded from the computation of diluted loss per share during periods in which losses are reported since the result would be anti-dilutive. As of June 30, 2020, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 1,068,979 and 73,754, respectively. As of June 30, 2019, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 287,854 and 0, respectively.

10. Restructuring and Severance Charges

The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. Employee severance costs are accrued when the restructuring actions are probable and estimable. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits, is recognized ratably over the future service period. The Company also records costs incurred with contract terminations associated with restructuring activities.

On September 30, 2019, prior to the Merger, NewLink adopted a restructuring plan to reduce its headcount by approximately 60%, which consisted primarily of clinical and research and development staff, and made several changes to senior leadership in order to conserve resources.

In addition to the restructuring, Charles J. Link, Jr, M.D. retired from NewLink and the NewLink board of directors, effective August 3, 2019 and Nicholas Vahanian retired from his position as the President and member of the board of directors, effective September 27, 2019, and his employment with the company ended on November 11, 2019.

In conjunction with the restructuring and departure of former NewLink executives, NewLink recorded restructuring and severance charges of $5.6 million during the year ended December 31, 2019. The following table shows the amount accrued for restructuring activities which is recorded within accrued expenses in the consolidated balance sheet (in thousands):

	Total Employee Severance Cost
Balance as of December 31, 2019	$ 4,700
Expensed	—
Cash Payments	3,731
Balance as of June 30, 2020	$ 969

11. Commitments and Contingencies

From time to time, claims are asserted against the Company arising in the ordinary course of business. In the opinion of management, liabilities, if any, arising from existing claims are not expected to have a material effect on the Company's earnings, financial position, or liquidity.

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York (the "Court for the Southern District of NY"), captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545 (the "Securities Action"). Subsequently, the Court for the Southern District of NY appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint asserting claims under the federal securities laws against NewLink, NewLink's former Chief Executive Officer Charles J. Link, Jr., and NewLink's former Chief Medical Officer and President Nicholas Vahanian, (collectively, the "Defendants"). The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to NewLink's investors. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. On March 29, 2018, the Court for the Southern District of NY dismissed the amended complaint for failure to state a claim, without prejudice, and gave the lead plaintiffs until May 4, 2018 to file any amended complaint attempting to remedy the defects in their claims. On May 4, 2018, the lead plaintiffs filed a second amended complaint asserting claims under the federal securities laws against the Defendants. Like the first amended complaint, the second amended complaint alleges that the Defendants made material false and/or misleading statements or omissions relating to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L that caused losses to NewLink's investors. The lead plaintiffs do not quantify any alleged damages in the second amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired NewLink's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the second amended complaint on July 31, 2018. On February 13, 2019, the Court for the Southern District of NY dismissed the second amended complaint for failure to state a claim, with prejudice, and closed the case. On March 14, 2019, lead plaintiffs filed a notice of appeal. The briefing on lead plaintiffs' appeal was completed in early July 2019 and oral argument before the Second Circuit Court of Appeals was held on October 21, 2019. In an opinion dated July 13, 2020, the Second Circuit Court of Appeals affirmed the district court's dismissal of the second amended complaint in part, vacated the district court's dismissal of the second amended complaint in part, and remanded the matter to the district court for further proceedings. On August 6, 2020, the Company filed a Petition for Rehearing en banc requesting reconsideration of portions of the opinion from the Second Circuit Court of Appeals and is awaiting the Court's determination concerning the petition. The Company intends to continue defending the Securities Action vigorously.

On or about April 26, 2017, Ronald Morrow filed a shareholder derivative lawsuit on behalf of NewLink in the Court for the Southern District of NY, against NewLink's former Chief Executive Officer Charles J. Link, Jr., NewLink's former Chief Medical Officer and President Nicholas Vahanian, and NewLink directors Thomas A. Raffin, Joseph Saluri, Ernest J. Talarico, III, Paul R. Edick, Paolo Pucci, and Lota S. Zoth (collectively, the "Morrow Defendants"), captioned Morrow v. Link., et al., Case 1:17-cv-03039 (the "Morrow Action"). The complaint alleges that the Morrow Defendants caused NewLink to issue false statements in its 2016 proxy statement regarding risk management and compensation matters in violation of federal securities law. The complaint also asserts state law claims against the Morrow Defendants for breaches of fiduciary duties, unjust enrichment, abuse of control, insider trading, gross mismanagement, and corporate waste, alleging that the Morrow Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L, awarded themselves excessive compensation, engaged in illegal insider trading, and grossly mismanaged NewLink. The plaintiff does not quantify any alleged damages in the complaint but seeks restitution for damages to NewLink, attorneys' fees, costs, and expenses, as well as an order directing that proposals for strengthening board oversight be put to a vote of NewLink's shareholders. The language for such proposals is not specified in the complaint. The plaintiff also contemporaneously filed a statement of relatedness, informing the Court for the Southern District of NY that the Morrow Action is related to Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545. On May 19, 2017, the plaintiff dismissed the Morrow Action without prejudice. Also on May 19, 2017, plaintiffs' counsel in the Morrow Action filed a new shareholder derivative complaint that is substantively identical to the Morrow Action, except that the plaintiff is Rickey Ely. The latter action is captioned Ely v. Link, et al., Case 17-cv-3799 (the "Ely Action"). By agreement of the parties and order dated June 26, 2017, the Court for the Southern District of NY temporarily stayed the Ely Action until the Securities Action is dismissed or otherwise finally resolved. Under the terms of the stay, the plaintiff in the Ely Action had until March 15, 2019 (30 days after dismissal of the Securities Action with prejudice) to file an amended derivative complaint or rest upon the current derivative complaint. By further agreement of the parties, dated March 15, 2019, the Ely Action will continue to be stayed pending the

outcome of the appeal in the Securities Action. If the Securities Action continues to be dismissed in its entirety following its appeal plaintiff in the Ely Action has agreed to withdraw or dismiss the action, with prejudice. The Company disputes the claims in the Ely Action and intends to defend against them vigorously.

12. Subsequent Events

On July 27, 2020, the Company entered into the PRV Transfer Agreement to sell its PRV to Merck. Under the terms of the License and Collaboration Agreement, Merck is entitled to 40% of the gross proceeds of the sale of the PRV. The Company and Merck agreed to value the PRV at $100.0 million, of which the Company will receive 60% or $60.0 million in gross proceeds. The purchase price will be paid in two installments: $34.0 million will be paid upon closing of the sale, and $26.0 million will be paid on January 11, 2021.

The PRV Transfer Agreement contains customary representations, warranties, covenants, and indemnification provisions subject to certain limitations. The transaction remains subject to customary closing conditions, including anti-trust review which we anticipate will be completed by early September 2020.

Additionally, in July 2020, the Company received the full refund of $4.5 million related to the income benefit recorded during the three months ended March 31, 2020 for pre-tax NOLs that were allowed to be carried back to prior years as a result of the CARES Act.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and such statements are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information available to our management as of the date hereof. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: the development plan for the Company's product candidate LUM-201 (ibutamoren) ("LUM-201"); the development plan for our existing pipeline and potential partnership and out-licensing opportunities; the timing of planned preclinical studies and clinical trials; the timing of and our ability to obtain regulatory approvals for our product candidates; the clinical utility of our product candidates; our plans to leverage our existing technologies to discover and develop additional product candidates; our intellectual property position; our ability to enter into strategic collaborations, licensing or other arrangements; our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; plans to develop and commercialize our product candidates; and other risks and uncertainties, including those described in Part II, Item 1A, "Risk Factors" of this Quarterly Report and in our other periodic reports filed from time to time with the Securities and Exchange Commission, or SEC, including our Annual Report on Form 10-K for the year ended December 31, 2019, our Quarterly Report for the quarter ended March 31, 2020, and Private Lumos's audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2019 included in our Current Report on Form 8-K/A, filed with the SEC on May 29, 2020. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including those risks. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. Such factors may be amplified by the COVID-19 pandemic and its potential impact on our business and the global economy.

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Overview

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. The Company's 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.

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.

Recent Events

On March 18, 2020, the Company, formerly known as NewLink, completed a merger in accordance with the terms of the Merger Agreement, pursuant to which Merger Sub merged with and into Private Lumos, with Private Lumos surviving as a wholly-owned subsidiary of NewLink.

Also on March 18, 2020, and prior to the Effective Time, the Company effected a 1-for-9 Reverse Stock Split and, following the Merger, changed its name to "Lumos Pharma, Inc." Unless otherwise noted herein, all references to share amounts give effect to the Reverse Stock Split. Following the completion of the Merger, the business being conducted by the Company became primarily the business conducted by Private Lumos, which is a biopharmaceutical company focused on the identification, acquisition, in-license, development, and commercialization of novel products for the treatment of rare diseases.

Lumos' current pipeline is focused on the future development of an orally administered small molecule, the growth hormone secretagogue ibutamoren, for three rare endocrine disorders.

For accounting purposes, Private Lumos is considered to have acquired NewLink in the Merger. NewLink's shares of common stock listed on The Nasdaq Global Market, previously trading through the Merger Date under the ticker symbol "NLNK", commenced trading on The Nasdaq Global Market, under the ticker symbol "LUMO", on Thursday, March 19, 2020. The accompanying results of operations give retroactive effect to the exchange ratio and change in par value for all periods presented.

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

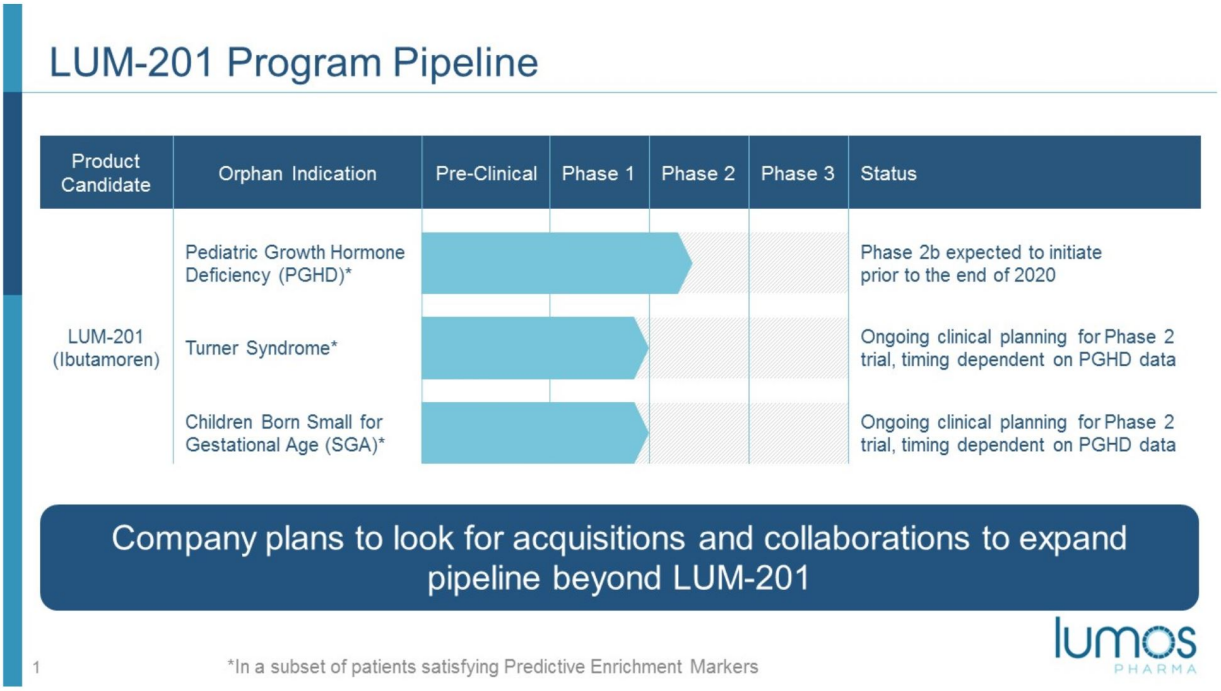
The results of operations and cash flows prior to the Merger Date, relate to Private Lumos. Subsequent to the Merger Date the information in these unaudited quarterly financial statements relates to the Company and its consolidated entities. All share and per share amounts in the financial statements and related notes have been retroactively adjusted, where applicable, for all periods presented to give effect to the exchange ratio applied in connection with the Merger and the Reverse Stock Split.

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. 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. On July 27, 2020, the Company entered into the PRV Transfer Agreement to sell the PRV to Merck. The Company and Merck agreed to value the PRV at $100.0 million, of which the Company will receive 60% or $60.0 million in gross proceeds. The purchase price will be paid in two installments: $34.0 million will be paid upon closing of the sale and $26.0 million will be paid on January 11, 2021.

LUM-201 Growth Hormone Secretagogue

Our pipeline is focused on the development of an orally administered small molecule, the growth hormone secretagogue 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 growth hormone ("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 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 separate Phase 2 clinical trials to study the effects of LUM-201 for Turner Syndrome and SGA in a certain subset of affected patients.

The graphic below depicts these indications with their respective development status.



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

If approved, LUM-201 has the potential to become the first approved oral GH secretagogue to treat rare endocrine disorders associated with GH deficiencies, starting with PGHD, providing an alternative to the current standard regimen of daily injections.

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

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

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

LUM-201 is intended to provide an oral treatment to stimulate the release of endogenous GH in PGHD patients who have a functional but reduced hypothalamic pituitary GH axis and are expected to respond to LUM-201. Lumos believes this group represents 50% to 60% of PGHD patients. Lumos is planning to initiate a clinical development program to study the effects of LUM-201 in PGHD by the end of 2020 with a Phase 2b study. Lumos has received a Study May Proceed letter from FDA after their review of our 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 study to address additional FDA comments that could increase Phase 3 registration readiness. The submitted trial is a randomized study testing three 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 a Phase 3 study.

Potential expansion of LUM-201 into additional endocrine indications

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

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

Lumos acquired LUM-201 from Ammonett Pharma LLC ("Ammonett") in July 2018. LUM-201 received Orphan Drug Designation ("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, 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, 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. 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 NIH from 2012 to February 2020.

The following relates to products in development by NewLink prior to the Merger:

IDO Pathway Inhibitors

In cancer, the IDO (indoleamine-2, 3-dioxygenase) pathway regulates immune response by suppressing T-cell activation, which enables cancer to avoid immune response. IDO is overexpressed in many cancers, both within tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor-draining lymph nodes, thereby promoting peripheral tolerance to tumor associated antigens ("TAAs"). When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system.

Currently, we have a small molecule portfolio primarily focused on the IDO pathway. Our small-molecule IDO pathway inhibitor product candidates that have previously been advanced into the clinic include indoximod and NLG802. Our product candidates are designed to counteract the above described immunosuppressive effects of the IDO pathway in cancer. Preclinical evidence supports the premise that indoximod stimulates the activation of antitumor T-cells through activation of mammalian target of rapamycin and modulation of signaling through the aryl hydrocarbon receptor.

To date, our IDO focused small molecules have been well tolerated in clinical trials. They are orally bioavailable and we believe they offer the potential to be synergistic with other cancer therapies such as radiation, chemotherapy, vaccination and immunotherapies involving other checkpoint inhibitors such as anti-PD-1, anti-programmed cell death ligand-1, or anti-cytotoxic T-lymphocyte antigen 4. Clinical data suggest an increase in clinical activity without adding significant toxicity.

More than 900 patients have been treated with indoximod to date and it has generally been well-tolerated, including in combination with PD-1 checkpoint inhibitors, various chemotherapy agents, radiation, and a cancer vaccine. A tablet formulation of indoximod hydrochloride for adult patients and a sprinkle formulation for pediatric indications have been developed. Both of these formulations of indoximod could be used in future clinical trials.

NLG802 is a prodrug of indoximod. NLG802 is intended to increase bioavailability and exposure to indoximod above levels currently achievable by direct oral administration of indoximod. Based on data from a Phase 1 dose escalation trial,

presented in May 2019 at the Immuno-Oncology 2019 World Congress, the treatment regimen was well tolerated with no NLG802-related serious adverse events reported. The recommended Phase 2 dose was established at 1452 mg BID based on achieving preclinical exposure levels required for pharmacodynamic effects of indoximod.

Two U.S. patents covering both the salt and prodrug formulations of indoximod were issued in the United States on August 15, 2017 and February 19, 2019, respectively, providing exclusivity until at least 2036. We are continuing to pursue international patent coverage for these formulations in some countries, and we are exploring the potential for further development and licensing opportunities but do not have an active program for the drug product candidate as of June 30, 2020.

Ebola Vaccine

In November 2014, NewLink entered into the NewLink Merck Agreement to develop and potentially commercialize our rVSVΔG-ZEBOV GP vaccine product candidate and other aspects of the vaccine technology. The rVSVΔG-ZEBOV GP vaccine product candidate was originally developed by the PHAC and is designed to utilize the rVSV vector to induce immunity against Ebola virus when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. Under the NewLink Merck Agreement, NewLink received an upfront payment of $30.0 million in October 2014, and in February 2015, NewLink received a milestone payment of $20.0 million.

In addition to milestone payments from Merck, NewLink was awarded contracts for development of the rVSVΔG-ZEBOV GP from the BARDA and the DTRA totaling $52.1 million during 2016 and $67.0 million during 2014 and 2015. Funds of $2.1 million were de-obligated from the DTRA grant awards in 2017. NewLink received total awards of $118.8 million. On April 26, 2018 NewLink entered into an agreement with Merck, DTRA and BARDA to transfer the government grants from BARDA and DTRA to Merck. The transfer was completed in June 2018 and Merck replaced NewLink as the prime contractor on all such grants.

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

Restructuring Charges

On September 30, 2019, prior to the Merger, NewLink adopted a restructuring plan to reduce its headcount by approximately 60%, which consisted primarily of clinical and research and development staff and made several changes to senior leadership in order to conserve resources.

In addition to the restructuring, effective August 3, 2019, Charles J. Link, Jr, M.D. retired from his position as the Chairman, Chief Executive Officer and Chief Scientific Officer and a member of the board of directors of NewLink, and Nicholas Vahanian retired from his position as the President and member of the board of NewLink, effective September 27, 2019, and his employment with NewLink ended on November 11, 2019.

As of June 30, 2020, the Company has $969,000 accrued relating to remaining payments expected to be paid out over the next twelve months. No expense was recorded during the six months ended June 30, 2020.

Corporate Information

Our executive offices are located at 4200 Marathon Blvd., Suite 200, Austin Texas. We have additional executive and administrative space in Ames, Iowa, with the lease ending in March 2021.

We incurred a net loss of $5.0 million for the six months ended June 30, 2020. We expect to continue to incur losses over the next several years as we incur expenses to complete our clinical trial programs, expand our pipeline and pursue regulatory approval of our product candidates.

Critical Accounting Policies and Significant Judgments and Estimates

We have prepared our financial statements in accordance with U.S. GAAP which requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, expenses and related disclosures at the date of the financial statements, as well as revenues and expenses during the reporting periods. As such, to understand our financial statements, it is important to understand our critical accounting policies. A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Actual results could, therefore, differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 4 to our condensed consolidated financial statements, we believe the following accounting policies to be critical in the preparation of our 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. 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 are capable of generating 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.

We considered all of the above factors when determining whether a business was acquired. In evaluating the Merger, we concluded that NewLink did not meet the definition of a business as it does not have the processes in place to generate outputs.

There are several methods that can be used to determine the fair value of acquired intangibles. We used the precedent transaction method under the market approach to estimate the value of the PRV. We relied on purchase prices indicated by actual precedent priority review voucher transactions that were reasonably comparable to the PRV owned by NewLink. The market approach requires several judgments and assumptions to determine the fair value including discount rates, probability assumption of sale, expected transaction sales price, and tax rates. A change in these assumptions would impact the consideration received and capitalized as part of the Merger. The change could be material. For example, a 3% change in the discount rate used would increase (decrease) the fair value of the PRV by approximately 2 to 4%.

The fair value assigned to the acquired in-process research and development assets was estimated based on the estimated expected net proceeds from the sales of these assets as intellectual property. These assets are no longer being actively pursued in further clinical development by the Company.

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*.

Recent Accounting Pronouncements

We do not believe that any recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

Results of Operations

Comparison of the Three Months Ended June 30, 2020 and 2019

Revenues. Revenues for the three months ended June 30, 2020 were $33,000, an increase of $33,000 from zero for the same period in 2019. The increase in revenue is attributable to $33,000 in licensing billings to Merck. We recognized licensing revenue during the three months ended June 30, 2020 for work we performed as a subcontractor of Merck.

Research and Development Expenses. Research and development expenses for the three months ended June 30, 2020 were $2.8 million, an increase of $882,000 from $1.9 million for the same period in 2019. The increase is primarily due to an increase of $877,000 in personnel-related and stock compensation expense, an increase of $480,000 in clinical trial expense and

an increase of $310,000 in supplies and other expense, offset by a decrease of $430,000 in contract manufacturing expense, and a decrease of $355,000 in legal and consulting expense.

General and Administrative Expenses. General and administrative expenses for the three months ended June 30, 2020 were $4.1 million, an increase of $3.4 million from $714,000 for the same period in 2019. The increase was due primarily to increases of $1.2 million in personnel-related and stock compensation expense, $1.2 million due to increased operating expenses for insurance, rent, supplies, and depreciation, and $969,000 in legal and consulting expense.

Income Tax Benefit. We recorded an income tax benefit of $1.4 million for the three months ended June 30, 2020. We recorded no income tax benefit for the three months ended June 30, 2019. The income tax benefit as of June 30, 2020 differs from the three months ended June 30, 2019 primarily due to the deferred benefit related to current period taxable loss that management anticipates will be utilized in the current year.

Net Loss. Net loss for the three months ended June 30, 2020 was $5.4 million compared to a net loss of $2.6 million for the same period in 2019. The net loss available to common shareholders for the three months ended June 30, 2020 was $5.4 compared to a net loss available to common shareholders of $3.3 million for the same period in 2019. The increase in net loss attributable to common shareholders compared to net loss is due to the accretion of preferred stock dividends of $0 and $758,000 for the three months ended June 30, 2020 and 2019, respectively. The basic and diluted weighted-average shares of common stock outstanding for the three months ended June 30, 2020 were 8,292,809, resulting in a basic and diluted loss per share available to common shareholders of $0.65. For the three months ended June 30, 2019, the basic and diluted weighted-average shares of common stock outstanding were 1,345,402, resulting in basic and diluted loss per share of $2.47.

Comparison of the Six Months Ended June 30, 2020 and 2019

Revenues. Revenues for the six months ended June 30, 2020 were $55,000, an increase of $55,000 from zero for the same period in 2019. The increase in revenue is attributable to $55,000 in licensing billings to Merck. We recognized licensing revenue during the six months ended June 30, 2020 for work we performed as a subcontractor of Merck.

Research and Development Expenses. Research and development expenses for the six months ended June 30, 2020 were $4.7 million, an increase of $1.3 million from $3.3 million for the same period in 2019. The increase is primarily due to additional expenses incurred as a result of the Merger including the write-off of the acquired NewLink in-process research and development of $426,000, and increases of $960,000 in personnel-related and stock compensation expense, $915,000 in clinical trial expense, and $99,000 in supplies and equipment, offset by decreases in legal and consulting expenses of $712,000 and contract manufacturing expense of $636,000.

General and Administrative Expenses. General and administrative expenses for the six months ended June 30, 2020 were $7.5 million, an increase of $6.1 million from $1.4 million for the same period in 2019. The increase was due primarily to increases of $2.0 million in personnel-related expense, including stock compensation expense, $2.0 million due to increased operating expenses for insurance, rent, supplies, and depreciation, $1.6 million in legal and professional fees incurred primarily due to the Merger, and $687,000 in legal and consulting expense, offset by a decrease in travel of $154,000.

Income Tax Benefit. We recorded an income tax benefit of $6.9 million for the six months ended June 30, 2020. We recorded no income tax benefit for the six months ended June 30, 2019. The income tax benefit as of June 30, 2020 differs from the six months ended June 30, 2019 primarily due to the benefit recorded as a result of our ability to carryback NOLs to the tax years beginning before December 31, 2017, specifically to the years ended December 31, 2014 and 2015, the release of the valuation allowance relating to Private Lumos NOL carryforwards, and current tax benefit that management anticipates will be utilized in the current year.

Net Loss. Net loss for the six months ended June 30, 2020 was $5.0 million compared to a net loss of $4.7 million for the same period in 2019. The net loss available to common shareholders for the six months ended June 30, 2020 was $5.7 million compared to a net loss available to common shareholders of $6.2 million for the same period in 2019. The increase in net loss attributable to common shareholders compared to net loss is due to the accretion of preferred stock dividends of $651,000 and $1.5 million for the six months ended June 30, 2020 and 2019, respectively. The basic and diluted weighted-average shares of common stock outstanding for the six months ended June 30, 2020 were 5,243,577, resulting in a basic and diluted loss per share available to common shareholders of $1.08. For the six months ended June 30, 2019, the basic and diluted weighted-average shares of common stock outstanding were 1,345,402, resulting in basic and diluted loss per share of $4.59.

Liquidity and Capital Resources

As of June 30, 2020, we had cash and cash equivalents of $72.7 million. We have historically funded our operations principally through the private placement of equity securities, public offerings of common stock, and license and milestone payments received under our collaboration agreements. We believe that our cash and cash equivalents on hand will be sufficient to fund our current operations through read out of the Phase 2b clinical trial.

We anticipate that we will continue to generate operating losses to the extent that we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

We may seek to sell additional equity or debt securities or obtain a credit facility if our available cash and cash equivalents are insufficient to satisfy our liquidity requirements or if we develop additional opportunities to do so. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research and development activities, which could harm our business.

Because of the numerous risks and uncertainties associated with the research and development of our product candidates, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results, and costs of clinical trials for our product candidates, and discovery and development activities related to new product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales, facilities, and distribution costs;
- the cost of manufacturing our product candidates and any products we commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- whether, and to what extent, we are required to repay our outstanding government provided loans;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the impact of public health crises such as the current COVID-19 pandemic or similar outbreaks, and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

Cash Flows

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

	Six Months Ended June 30,	
	2020	2019
Net cash used in operating activities	$ (16,410)	$ (4,471)
Net cash provided by investing activities	84,165	—
Net cash used in financing activities	(10)	—
Net increase (decrease) in cash and equivalents	$ 67,745	$ (4,471)

For the six months ended June 30, 2020 and 2019, we used cash of $16.4 million and $4.5 million, respectively, for our operating activities. The increase in cash used in operating activities was primarily due to the Merger activity and changes in working capital for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019.

For the six months ended June 30, 2020 our investing activities provided cash of $84.2 million compared to none for the six months ended June 30, 2019. The cash provided by investing activities during the six months ended June 30, 2020 was due to $84.2 million in cash acquired in connection with the Merger.

For the six months ended June 30, 2020 our financing activities used cash of $10,000 compared to none for the six months ended June 30, 2019. The cash used in financing activities during the six months ended June 30, 2020 was due to proceeds of sales of our common stock under our employee stock purchase program of $6,000 offset by payments of $16,000 on notes payable.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of June 30, 2020 and December 31, 2019, we had cash and cash equivalents of $72.7 million and $5.0 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company’s principal executive officer and principal financial officer have concluded, based on an evaluation of the Company’s disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, as amended (Exchange Act), Rules 13a-15(e) or 15d-15(e)) as required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15 that, as of June 30, 2020, the Company’s disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

In connection with the evaluation of the Company's internal control over financial reporting that occurred during the quarter ended June 30, 2020, which is required under the Exchange Act by paragraph (d) of Exchange Rules 13a-15 or 15d-15 (as defined in paragraph (f) of Rule 13a-15), management determined that there was no change that materially affected or is reasonably likely to materially affect internal control over financial reporting.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are the subject of, or a party to, a number of pending or threatened legal actions, contingencies and commitments involving a variety of matters. Except as described below, there have been no material changes to the legal proceedings previously disclosed in our Annual Report on Form 10-K, as updated in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020.

As previously disclosed in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, on or about May 12, 2016, Trevor Abramson filed the Securities Action in the Court for the Southern District of NY. Subsequently, the Court for the Southern District of NY appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint asserting claims under the federal securities laws against the Defendants. The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. On March 29, 2018, the Court for the Southern District of NY dismissed the amended complaint for failure to state a claim, without prejudice, and gave the lead plaintiffs until May 4, 2018 to file any amended complaint attempting to remedy the defects in their claims. On May 4, 2018, the lead plaintiffs filed a second amended complaint asserting claims under the federal securities laws against the Defendants. Like the first amended complaint, the second amended complaint alleges that the Defendants made material false and/or misleading statements or omissions relating to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L that caused losses to the Company's investors. The lead plaintiffs do not quantify any alleged damages in the second amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the second amended complaint on July 31, 2018. On February 13, 2019, the Court for the Southern District of NY dismissed the second amended complaint for failure to state a claim, with prejudice, and closed the case. On March 14, 2019, lead plaintiffs filed a notice of appeal. The briefing on lead plaintiffs' appeal was completed in early July 2019 and oral argument before the Second Circuit Court of Appeals was held on October 21, 2019. In an opinion dated July 13, 2020, the Second Circuit Court of Appeals affirmed the district court's dismissal of the second amended complaint in part, vacated the district court's dismissal of the second amended complaint in part, and remanded the matter to the district court for further proceedings. On August 6, 2020, the Company filed a Petition for Rehearing en banc requesting reconsideration of portions of the opinion from the Second Circuit Court of Appeals and is awaiting the Court's determination concerning the petition. The Company intends to continue defending the Securities Action vigorously.

Item 1A. RISK FACTORS

RISK FACTORS

Investing in our common stock involves significant risks, some of which are described below. In evaluating our business, investors should carefully consider the following risk factors. These risk factors contain, in addition to historical information, forward-looking statements that involve substantial risks and uncertainties. Our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below. The order in which the following risks are presented is not intended to reflect the magnitude of the risks described. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to our Financial Condition and Capital Requirements

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We do not have any products approved for sale, and we are currently focused on developing our only product candidate, LUM-201. Evaluating our performance, viability or future success will be more difficult than if we had a longer operating history or approved products on the market. We continue to incur significant research and development and general and administrative expenses related to our

operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. We have incurred significant operating losses in each year since our inception and expect to incur substantial and increasing losses for the foreseeable future. As of June 30, 2020, we had an accumulated deficit of $65.3 million. As a result of the PRV Transfer Agreement entered into with Merck on July 27, 2020, we may have taxable net income during the year ended December 31, 2020, however, due to the step up to fair value of the PRV asset recorded in conjunction with the Merger, we do not expect to achieve operating income for 2020 or for the foreseeable future.

To date, we have financed our operations primarily through private placements of our convertible preferred stock. We have devoted substantially all of our efforts to research and development, including clinical trials, but have not completed development of any product candidate. We anticipate that our expenses will increase substantially as we:

- continue the research and development of our only product candidate, LUM-201, and any future product candidates;
- pursue clinical trials of LUM-201, including the Phase 2b Trial of LUM-201 that we expect to initiate in by the end of 2020;
- seek to in-license additional product candidates and incur any future costs to develop these product candidates;
- seek regulatory approvals for LUM-201 and any future product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize LUM-201 or other future product candidates if they obtain regulatory approval, including process improvements in order to manufacture LUM-201 or other future product candidates at commercial scale; and
- enhance operational, financial and information management systems and hire more personnel, including personnel to support development of LUM-201 and any future product candidates and, if a product candidate is approved, its commercialization efforts.

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

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

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

- complete development activities, including our planned Phase 2b and Phase 3 clinical trials of LUM-201, successfully and on a timely basis;
- demonstrate the safety and efficacy of LUM-201 to the satisfaction of the FDA and obtain regulatory approval for LUM-201 and future product candidates, if any, for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- set a commercially viable price for our products;
- establish and maintain supply and manufacturing relationships with reliable third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;

- develop a commercial organization capable of sales, marketing and distribution of any products for which we obtain marketing approval in markets where we intend to commercialize independently;
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- achieve market acceptance of our approved products, if any;
- establish, maintain and protect our intellectual property rights and avoid third-party patent interference or patent infringement claims; and
- attract, hire and retain qualified personnel.

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

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

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

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

- the rate of progress and cost of our clinical trials;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient, cost-effective, and scalable manufacturing process for LUM-201 and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties to obtain finished products that are appropriately packaged for sale;
- the costs of commercialization activities if LUM-201 or any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by us or future partners;
- a continued acceptable safety profile following any marketing approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements;
- the emergence of competing technologies or other adverse market developments; and
- the costs of attracting, hiring and retaining qualified personnel.

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

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

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under any potential future collaboration and license agreements and sales of its product candidates, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our Board, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

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

- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

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

Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code").

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

Based on Section 382 ownership change analyses, we believe that from our inception through June 30, 2019, we experienced Section 382 ownership changes in September 2001 and March 2003, and BPS experienced Section 382 ownership changes in January 2006 and January 2011.

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

These ownership changes limited our ability to utilize federal net operating loss carryforwards and certain other tax attributes that accrued prior to the respective ownership changes of us and our subsidiaries and may continue to limit our ability to utilize such attributes in the future.

Additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders.

Accounting pronouncements may impact our reported results of operations and financial position.

U.S. GAAP and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new pronouncements or the application of existing pronouncements to changes in our business could significantly alter our reported financial statements and results of operations.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to meet compliance obligations.

As a public company, we incur significant legal, accounting and other expenses to comply with reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), as well as rules subsequently implemented by the SEC and The Nasdaq Global Market. Meeting the requirements of these rules and regulations entails significant legal and financial compliance costs, makes some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel devote a substantial amount of time to these compliance requirements. In addition, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to publish a report by our management on our internal control over financial reporting. To achieve compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which has been both costly and challenging. To maintain compliance on

an ongoing basis, we will need to dedicate internal resources, engage outside consultants and adopt a detailed work plan. Despite our effort, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

The comprehensive tax reform bill of 2017 could adversely affect our business and financial condition.

On December 22, 2017 the Tax Act was signed into law. The Tax Act significantly revised the Code and included, among other things, significant changes to corporate taxation, including a reduction of the corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income for net operating losses arising in taxable years beginning after December 31, 2017 and elimination of net operating loss carrybacks for net operating losses arising in taxable years beginning after December 31, 2017, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act did not have a material impact on our business. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to the Tax Act and the potential tax consequences of investing in or holding our common stock.

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

For the three and six months ended June 30, 2020, we recorded an income tax benefit of $1.4 million and $6.9 million, respectively. Our income tax rate differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to the benefit of $4.5 million recorded as a result of the CARES Act. Additionally, the income tax benefit three and six months ended June 30, 2020 includes $1.4 million and $2.4 million, respectively, for the release of the valuation allowance related to Private Lumos NOLs and a current period benefit for losses the Company anticipates will be offset by future income. Our effective income tax rate, as well as our relative domestic and international tax liabilities, will depend in part on the allocation of any future income among different jurisdictions. In addition, various factors may have favorable or unfavorable effects on our effective income tax rate in individual jurisdictions or in the aggregate. These factors include whether tax authorities agree with our interpretations of existing tax laws, any required accounting for stock options and other share-based compensation, changes in tax laws and rates (including the recently enacted U.S. federal income tax law changes), our future levels of research and development spending, changes in accounting standards, changes in the mix of any future earnings in the various tax jurisdictions in which we may operate, the outcome of any examinations by the U.S. Internal Revenue Service or other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings. The effect on our income tax liabilities resulting from the above-mentioned factors or other factors could have a material adverse effect on our results of operations.

Risks Related to the Development and Commercialization of our Product Candidate

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

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

We cannot commercialize LUM-201 or any future product candidates in the United States without first obtaining regulatory approval for the product from the FDA, nor can we commercialize LUM-201 or any future product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. The FDA review process typically takes years to complete and approval is never guaranteed. Before obtaining regulatory approvals for the commercial sale of LUM-201 for a target PGHD indication or our future product candidates, we generally must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical trials that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. We are pursuing the same regulatory pathway for LUM-201 followed by most of the approved rhGH products and long-acting GH products under development for a subset of PGHD patients. We intend to study treatment naïve and previously-treated patients by conducting trials including a six-month Phase 2b dose-finding trial and a Phase 3 clinical trial with a primary endpoint of 12

month mean height velocity that is intended to support regulatory approval. If we must conduct additional or different trials than prior rhGH products were required to complete, this could increase the amount of time and expense required for regulatory approval of LUM-201, if any. In addition, while the available growth data from published studies of approved rhGH therapy products suggest that six and 12 months mean height velocities are well correlated, it is possible that LUM-201, due to its unique properties, will produce different results. If the six months mean height velocities that we observe for LUM-201 in the planned Phase 2b Trial do not correlate to 12 month mean height velocities that we ultimately observe in any Phase 3 clinical trial that we may conduct, LUM-201 may not achieve the required primary endpoint in the Phase 3 clinical trial, and LUM-201 may not receive regulatory approval. Moreover, obtaining regulatory approval for marketing of LUM-201 in one country does not ensure we will be able to obtain regulatory approval in other countries, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

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

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

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

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

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

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

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

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

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

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

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

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

If we make changes to any of our product candidates, additional clinical trials may be required resulting in additional costs and delays.

We have an ongoing research program to investigate potential opportunities to improve the potency, efficacy and/or safety profile of some of our product candidates through modifications to their formulations or chemical compositions. These efforts may not be successful. If a new formulation or composition appears promising, we may decide to undertake clinical development of such formulation or composition even if an existing product candidate has shown acceptable safety and efficacy in clinical trials. The nature and extent of additional clinical trials that might be required for a new formulation or composition would depend on many factors. If we were to decide to pursue clinical development of a new formulation or composition, we would incur additional costs and the timeline for potential commercialization would be delayed. There can be no assurance that any new formulation or composition would prove to be safe or effective or superior to an existing product candidate. Any delay in commercialization of a new formulation or composition may adversely affect our competitive position.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle, including by allowing IND applications to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. Furthermore, our resource allocation decisions and

our decisions about whether and how to develop or commercialize any particular product candidate may be based on evaluations of the scientific and commercial potential or target market for the product candidate that later prove to be materially inaccurate. If we enter into collaborations, licensing or other royalty arrangements to develop or commercialize a particular product candidate, we may relinquish valuable rights to that product candidate in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, have, and could continue to adversely impact our business, including our planned clinical trials.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019, or COVID-19, surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States. In response to the spread of COVID-19, we have closed our executive offices with our employees continuing their work outside of our offices.

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

- interruption or delays in the operations of the U.S. Food and Drug Administration and comparable foreign regulatory agencies, which may impact timelines for regulatory submission, trial initiation and regulatory approval;
- interruption or delays in our contract research organizations ("CROs") and collaborators meeting expected deadlines or complying with regulatory requirements related to preclinical development activities, preclinical studies and planned clinical trials;
- interruptions of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations ("CMOs") due to staffing shortages, productions slowdowns or stoppages and disruptions in delivery systems;
- delays or difficulties in any planned clinical site initiation, including difficulties in obtaining IRB approvals, recruiting clinical site investigators and clinical site staff;
- delays or difficulties in enrolling patients in clinical trials;
- increased rates of patients withdrawing from any planned clinical trials following enrollment as a result of contracting COVID-19 or being forced to quarantine;
- diversion of healthcare resources away from the conduct of our preclinical development activities, preclinical studies and planned clinical trials, including the diversion of hospitals serving as any potential clinical trial sites and hospital staff supporting the conduct of our planned clinical trials;
- interruption of planned key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and planned clinical study endpoints;
- limitations on employee or collaborator resources that would otherwise be focused on the conduct of our preclinical development activities, preclinical studies and planned clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions; and
- reduced ability to engage with the medical and investor communities due to the cancellation of conferences scheduled throughout the year.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct preclinical development activities, preclinical studies and planned clinical trials and our business generally, and has had and could continue to have a material adverse impact on our operations and financial condition and results.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 epidemic. As a result, our ability to raise capital through any future sales of our common stock or such

sales may be on unfavorable terms. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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

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

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

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

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

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

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

We have identified several aspects of the Phase 2b Trial protocols that could potentially delay or prevent our ability to receive regulatory approval or commercialize LUM-201. For example, we may be administering LUM-201 at dose levels that are not as efficacious and/or safe as other rhGH therapies. The Phase 2b Trial will test doses of LUM-201 that are equal to, and two and four times higher than, the highest doses tested in the multiple dose Merck Trials. These higher doses were never tested in adults or children in a multiple dose trial in the Merck Trials and, even if the trials are able to show that such higher doses increase efficacy, such higher doses may not be as safe as the doses tested in the Merck Trials. As a result, frequent safety assessments may be required during the trial.

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

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials may be larger than we anticipate, enrollment of subjects who meet our inclusion criteria in these clinical trials may be insufficient or slower than we anticipate, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our existing supply of the LUM-201 Active Pharmaceutical Ingredient (the "API") was manufactured more than 20 years ago and, while we have conducted testing and believe this supply is suitable for clinical use, it may unexpectedly become unusable or documentation concerning this supply may be in the possession of third parties and become unavailable over time;
- the cost of clinical trials or the manufacturing of our product candidates may be greater than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that our product candidates have unanticipated serious adverse events or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;
- regulators may not approve our proposed clinical development plans;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

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

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

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

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

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

Even if we receive regulatory approval for LUM-201, certain factors may limit the market for LUM-201 or put the product at a competitive disadvantage relative to alternative therapies. For instance, we believe that the treatment will only be effective for approximately 50% to 60% of PGHD patients, and approximately 50% for patients with either SGA or Turner Syndrome, and the actual percentages could be substantially lower. Certain jurisdictions such as Australia and the European Union have different diagnostic criteria for diagnosing PGHD and as a result, the market for LUM-201 in those jurisdictions is smaller. In addition, there are a number of challenges that LUM-201 would face to obtain acceptance and use by physicians. Physicians will need to conduct additional testing to identify their patients who would be eligible for LUM-201 treatment. Approved products that would compete with LUM-201 have been used for many years or decades with an excellent safety profile. It will

take a number of years of results of LUM-201 to provide the comfort level that may be necessary to satisfy some physicians and patient families. Some physicians may feel the benefits of an oral product do not outweigh limitations. For example, the mean annual growth velocity for LUM-201 treated patients included in the trial (Predictive Enrichment Marker ("PEM")-Positive) may be substantially lower, despite meeting non-inferiority study requirements, than such mean for all rhGH treated PGHD patients. These factors could limit the size of the market LUM-201 intends to address and the rate of market acceptance, which could materially impair our ability to generate revenue.

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

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

At the doses tested previously in the Merck Trials, LUM-201 was generally well-tolerated in children with the most commonly reported adverse events being digestive systems events, including appetite increase. Mild elevations in liver enzymes without accompanying changes in bilirubin were also reported. To our knowledge, no serious drug-related adverse events have been reported in children treated with LUM-201 to date. However, we cannot assure you that adverse events from LUM-201 in current or future clinical trials will not prompt the discontinuation of the development of LUM-201. Similarly, our future product candidates may cause serious adverse events or have other properties that could delay or prevent their regulatory approval. As a result of these adverse events or further safety or toxicity issues that we may experience in its clinical trials in the future, we may not receive approval to market LUM-201 or any future product candidates, which could prevent us from ever generating revenue or achieving profitability. Results of our trials could reveal an unacceptably high severity or prevalence of adverse events. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order it to cease further development of or deny approval of its product candidates for any or all targeted indications. Any drug-related adverse events could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition, cash flows and future prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

We have an existing supply of the LUM-201 API obtained in connection with the Asset Purchase Agreement by and between Lumos and Ammonett (the "APA") and the exclusive, worldwide license and collaboration agreement entered into in November 2014 with Merck (the "Lumos Merck Agreement") that we believe will be sufficient for our Phase 2b Trial, subject to FDA review. The LUM-201 API has never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, and timely availability of raw materials. Even if we could otherwise obtain regulatory approval for LUM-201, there is no assurance that any manufacturer we arrange will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If any manufacturer is unable to begin production in a timely and efficient manner or produce sufficient quantities of the approved product for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

Although a substantial amount of our efforts will focus on the continued clinical testing and potential approval of our product candidate, LUM-201, a key element of its long-term growth strategy is to acquire, develop, and/or market additional products and product candidates. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into its current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured profitably or achieve market acceptance.

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

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

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

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

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

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

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

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

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

We may form strategic alliances in the future, and we may not realize the benefits of such alliances.

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

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

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

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

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

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

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

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical trials or cancellation of trials;

- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

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

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

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

Under the NewLink Merck Agreement, we have ongoing obligations related to ERVEBO®, which may result in greater costs than we estimate, yet we will receive limited revenues, if any, from any future sales of ERVEBO®.

Even now that ERVEBO® has been approved, a number of factors may adversely affect commercial sales of such product and we may receive limited or no revenues under the NewLink Merck Agreement. For example, lack of familiarity with the viral vaccine and potential adverse events associated with vaccination may adversely affect physician and patient perception and uptake of such product. Furthermore, there are no assurances that the vaccine will be approved for inclusion in government stockpile programs, which may be material to the commercial success of the product candidate, either in the United States or abroad. Finally, in certain cases, our obligations to pay royalties to PHAC may exceed the royalties we receive from Merck.

Some of our product candidates have been studied, or in the future may be studied, in clinical trials co-sponsored by organizations or agencies other than us, or in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.

We have in the past and currently supply indoximod in support of Phase 2 investigator-initiated clinical trials, and we provided clinical supply of dorgenmeltucel-L in support of a Phase 2 investigator-initiated clinical trial. Our Ebola vaccine product candidate was studied in clinical trials in West Africa. We may continue to supply and otherwise support similar trials in the future. However, because we are not the sponsors of these trials, we do not control the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment, and, as a result, are subject to risks associated with the way these types of trials are conducted, in particular should any problems arise. These risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data.

Risks Related to the Operation of our Business

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

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

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

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

As of June 30, 2020, we had 28 employees. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, commercial development and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

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

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

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

In addition to the disruptions we may face as a result of the COVID-19 pandemic, our operations could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase its costs and expenses.

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

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

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

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

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

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

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

Our employees, independent contractors and consultants, principal investigators, CROs, CMOs and other vendors, and any future commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors and consultants, principal investigators, CROs, CMOs and other vendors, and any future commercial partners may engage in fraudulent conduct or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with our manufacturing standards or those required by cGMP, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, and to report financial information or data accurately or disclose unauthorized activities to them. The misconduct of our employees and other service providers could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have implemented a code of business ethics and conduct, but it is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity, such as the implementation of a quality system which entails vendor audits by quality experts, may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. For example, if one of our manufacturing partners was placed under a consent decree, we may be hampered in our ability to manufacture clinical or commercial supplies.

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

Under our license agreement with Merck and its APA with Ammonett, we are obligated to use commercially reasonable and diligent efforts to develop and commercialize LUM-201. We are also obligated to make substantial milestone payments and royalties to both Merck and Ammonett, which may limit our future profitability and our ability to enter into marketing partnership agreements. If we fail to fulfill our obligations under our contractual commitments to Merck, Ammonett, or any other counterparty, the counterparties could terminate the exclusive, worldwide license and collaboration agreement entered

into in November 2014, the Lumos Merck Agreement, or make claims against us under both agreements, which could have a materially adverse effect on our business, results of operations and prospects.

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

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

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

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

We currently have limited experience in, and we do not own facilities for, clinical-scale manufacturing of our sole product candidate, LUM-201, and we currently rely and may continue to rely upon a single third-party CMO to manufacture and supply drug product for our clinical trials of LUM-201. The manufacture of pharmaceutical products in compliance with the FDA's cGMP requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs, yields, and quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements and foreign regulations. If any manufacturer contracted by us were to encounter any of these difficulties or otherwise fail to comply with its obligations to us or under applicable regulations, our ability to provide study drugs in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

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

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

significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to us.

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

We may enter into collaboration agreements with third parties with respect to LUM-201 for the commercialization of this candidate in or outside the United States, or with respect to future product candidates for commercialization in or outside the United States. Our likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates, and limited control over certain intellectual property rights related to the collaboration as well as other elements of the collaboration we would be relying on our collaborators for. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Any termination or disruption of collaborations could result in delays in the development of product candidates, increase our costs to develop the product candidates or the termination of development of a product candidate.

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

As part of our strategy, we plan to explore a variety of possible strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in the process of seeking appropriate strategic collaborators, and such collaborations can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

We are required under the NewLink Merck Agreement, and we may be required under other collaborations, to relinquish important rights to and control over the development of our product candidates to our collaborators or otherwise be subject to unfavorable terms.

Our collaborations, including any future strategic collaborations we enter into, could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- other than under the NewLink Merck Agreement, we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;

- strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may also adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

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

We are subject to laws and regulations enforced by the FDA, the Drug Enforcement Agency, foreign health authorities and other regulatory requirements, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Food, Drug and Cosmetic Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of our products, materials used to develop and manufacture our product candidates, and resulting waste products. Although we believe that our safety procedures for handling and disposing of such materials, and for killing any unused microorganisms before disposing of them, comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Risks Related to our Intellectual Property

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

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

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

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

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

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

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

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

Interference or derivation proceedings provoked by third parties or brought by the United States Patent and Trademark Office (the "USPTO") or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to patents and patent applications. We or our licensers may become involved in proceedings, including oppositions, interferences, derivation proceedings inter partes reviews, patent nullification proceedings, or re-examinations, challenging our patent rights or the patent rights of others, and the outcome of any such proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, important patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, data which form the basis of our key patent and patent applications were the result of certain clinical trials conducted by Merck, and disagreements may therefore arise as to the ownership or validity of any intellectual property developed pursuant to such relationship. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

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

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

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

For example, Merck, which has sublicensed our Ebola vaccine product candidate under the NewLink Merck Agreement, has received correspondence from Yale University asserting that it owns certain intellectual property rights with respect to the Ebola vaccine that they assert, among other things, may need to be licensed by Merck. We also received correspondence from Yale University relating to the research and construction of the Ebola vaccine product by our licensor PHAC. If Merck were required to pay royalties to Yale University, that could result in a reduction of Merck's royalty obligations to us. If Merck otherwise suffered damages as a result of claims by Yale University, it is possible that Merck could seek indemnification from us.

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

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

In addition to our products and patented technology, we rely upon confidential proprietary information, including trade secrets, unpatented know-how, technology and other proprietary information, to develop and maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding its competitive position in the market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. These agreements are designed to protect our proprietary information; however, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets, or that technology relevant to our business will not be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect trade secrets and confidential information to the same extent as the laws of

the United States. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents.

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

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

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

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

Risks Related to Government Regulation

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

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our collaboration partners are permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA. Neither we nor our collaboration partners have submitted an application or received marketing approval for LUM-201 or any future product candidates. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with the FDA and other applicable United States and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following:

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

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

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

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

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

Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

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

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

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

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

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

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

We intend to seek a distribution and marketing partner for LUM-201 outside the United States and may market future products in international markets. In order to market our future products in regions such as the EEA, Asia Pacific, and many other foreign jurisdictions, we must obtain separate regulatory approvals.

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

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

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

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system in ways that could affect its future revenue and profitability and the future revenue and profitability of its potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would

result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the PPACA was enacted in 2010. The PPACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The PPACA, among other things:

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

While the United States Supreme Court upheld the constitutionality of most elements of the PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. For example, on December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. Although the Texas U.S. District Court Judge, as well as the presidential administration and the CMS have stated that the ruling will have no immediate effect pending appeal of the decision. On July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case. 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. We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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

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

- our ability to set a price that we believe is fair for our products;

- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

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

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

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

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following, without limitation, are:

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

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state laws require biotechnology companies to report information on the pricing of certain drug products, and certain state and local laws require the registration of pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the European Union is governed by the General Data Protection Regulation (the "GDPR"), which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union.

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

The biopharmaceutical industry is subject to significant regulation and oversight in the United States, in addition to approval of products for sale and marketing; our failure to comply with these laws could harm our results of operations and financial condition.

In addition to FDA restrictions on marketing of biopharmaceutical products, our operations may be directly, or indirectly through our relationships with healthcare providers, customers and third-party payers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute. These laws may impact, among other things, our proposed sales, and education programs, and these laws have been applied to restrict certain marketing practices in the biopharmaceutical industry. In addition, we may be subject to patient privacy regulation by both the U.S. federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, among others, the following:

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

- The federal civil False Claims Act prohibits any person or entity from knowingly presenting, or causing to be presented, to the federal government a claim for payment or approval that is false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Several pharmaceutical and other health-care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of off-label promotion. Private parties may initiate qui tam whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit.

- HIPPAA imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- HIPAA, as amended by HITECH and their implementing regulations imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization on covered entities, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information.

- The FDCA prohibits, among other things, the adulteration or misbranding of drugs and medical devices.

- The federal Physician Payments Sunshine Act, and its implementing regulations require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services (CMS), information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

- Analogous state laws and regulations include: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information and that require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. It is possible that some of our business activities could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business, financial condition and results of operations.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that required that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This

Executive Order included a budget neutrality provision that required the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations that can be repealed to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the United States Office of Management and Budget on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. Further, on February 24, 2017, President Trump issued an Executive Order requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification. It is difficult to predict how these requirements will continue to be enforced, the extent to which they will continue to impact the FDA's ability to exercise its regulatory authority, and the negative impact they may have on our business.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and could decline significantly.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including those described elsewhere in this "Risk Factors" section of this Quarterly Report on Form 10-Q and the following:

- the impact of the COVID-19 pandemic;
- new products, product candidates or new uses for existing products introduced or announced by our strategic collaborators, or our competitors, and the timing of these introductions or announcements;
- actual or anticipated results from and any delays in our clinical trials due to the COVID-19 pandemic or other factors, as well as results of regulatory reviews relating to the approval of our product candidates;
- variations in the level of expenses related to any of our product candidates or clinical development programs, including those relating to the timing of invoices from, and other billing practices of, our clinical research organizations and clinical trial sites;
- expenses related to, or our ability or perceived ability to secure, an adequate supply of any future products approved for commercial sale;
- the expiration on September 14, 2020 of the lock-up agreements that restrict the ability of our executive officers and directors and certain principal stockholders from transferring shares of the Company's capital stock;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures and capital commitments;
- the commercial or clinical success or failure, or perceived success or failure, of our collaborators, including Merck;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- media attention, or changes in media attention, given to cancer and cancer treatment, the recent Ebola epidemic and efforts to develop treatments and vaccines for Ebola, or any other condition or disease that our product candidates are being developed to treat;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- the financial projections we may provide to the public, and any changes in these projections or our failure to meet these projections;

- deviations from securities analysts' estimates or the impact of other analyst rating downgrades by any securities analysts who follow our common stock;
- other events or factors, including those resulting from public health crises such as pandemics, political uncertainty, war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. We are currently party to the securities class action litigation described in Part II, Item 1 of this Quarterly Report on Form 10-Q under the heading "Legal Proceedings." This litigation and others like it that could be brought against us in the future could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of June 30, 2020, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 48.9% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after June 30, 2020. These stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our Board, future issuances of our common stock or other securities, declarations of dividends on our common stock and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock. In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares may be distributed and subsequently voted.

The lock-up agreements executed at the time of our Merger expire on September 14, 2020 and future sales of shares by our existing stockholders could cause our stock price to decline substantially.

The lock-up agreements executed at the time of our Merger expire on September 14, 2020 and, upon the expiration of such lock-up agreements, an additional approximately 5.1 million shares of our common stock may be sold into the public market. If stockholders who had signed lock-up agreements or other existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline substantially. As of June 30, 2020, there were a total of approximately 8.3 million shares of our common stock outstanding. Upon the expiration of the lock-up agreements, substantially all of such outstanding shares will be eligible for sale in the public market.

Our amended and restated bylaws ("Bylaws") designates the state courts in the State of Delaware of, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against us or our directors, officers, or employees.

Our Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on behalf of the corporation; (2) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, other employee or stockholder of the corporation to the corporation or to the corporation's

stockholders; (3) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or the Bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or (4) any action asserting a claim governed by the internal affairs doctrine. This choice of forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, or the Exchange Act, or any claim for which the federal courts have exclusive jurisdiction.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits. Furthermore, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

We do not anticipate that that we will pay any cash dividends in the foreseeable future.

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

Provisions in our certificate of incorporation, our by-laws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our certificate of incorporation, our by-laws or Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. These provisions include:

- the division of our Board into three classes with staggered, three-year terms;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to call special meetings;
- limitations on the ability of stockholders to remove directors or amend our by-laws; and
- the ability of our Board to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person that together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

The holdings of our stockholders may be diluted, and the prices of our securities may decrease, by the exercise of outstanding stock options or by future issuances of securities by us.

We may issue additional common stock, preferred stock, RSUs, or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, RSUs, or securities convertible into or exchangeable for our common stock or the exercise of stock options would dilute existing investors and could adversely affect the price of our securities. In addition, such securities may have rights senior to the rights of securities held by existing investors.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

On August 12, 2020, we entered into Amendment No. 1 to the Lumos Merck Agreement with Merck (the “Lumos Merck Agreement Amendment”). The Lumos Merck Agreement grants Lumos a worldwide, exclusive, sublicensable (subject to Merck’s consent in the United States, specified European countries and Japan, such consent not to be unreasonably withheld) license under specified patents and know-how to develop, manufacture and commercialize LUM-201 for the treatment or prevention of any and all indications, excluding Autism Spectrum Disorders. Pursuant to the Lumos Merck Agreement Amendment, we obtained from Merck a worldwide, non-exclusive, sublicensable (subject to Merck’s consent in the United States, specified major European countries and Japan, such consent not to be unreasonably withheld) license under the specified patents and know-how that are the subject of our exclusive license to develop, manufacture and commercialize LUM-201 for diagnostic purposes, excluding Autism Spectrum Disorders. Additionally, we and Merck agreed that, among other things, (a) our sublicensees have the right to grant further sublicenses (subject to Merck’s prior written consent, not to be unreasonably withheld), and (b) if we provide Merck with a notice that we intend to enter into a development or commercial arrangement with a third party with respect to LUM-201 for the treatment or prevention of any and all indications (excluding Autism Spectrum Disorders) in the United States, specified European countries or Japan, and either Merck does not submit terms for such arrangement within a specified period of time or we and Merck do not (despite good faith negotiations) enter into a definitive agreement with Merck for such arrangement within a specified period of time after Merck’s submission of such terms, then we have the right, for a specified period of time thereafter, to enter into a development or commercial arrangement with any third party with respect to LUM-201, without having to submit a new notice to Merck with respect to such arrangement, and if any such third party agreement is entered into, such third party may hire a contract sales force for LUM-201 without Merck’s prior written consent.

The foregoing description of the Lumos Merck Agreement Amendment is qualified in its entirety by reference to the complete text of such agreement, a copy of which is attached as Exhibit 10.4 to this Quarterly Report on Form 10-Q.

ITEM 6. EXHIBITS

The following exhibits are filed with this Form 10-Q or incorporated herein by reference to the document set forth next to the exhibit listed below. Where so indicated, exhibits that were previously filed are incorporated by reference.

Exhibit Number		Description	Incorporated By Reference			Filed Herewith
			Form	Filing Date	Number	
3.1		Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2		Certificate of Amendment to Restated Certificate of Incorporation filed on May 10, 2013	8-K	5/14/2013	3.1	
3.3		Certificate of Amendment to Certificate of Incorporation to Effect the Reverse Stock Split	8-K	3/18/2020	3.1	
3.4		Certificate of Amendment to Certificate of Incorporation to Effect the Name Change	8-K	3/18/2020	3.2	
3.5		Amended and Restated Bylaws	8-K	9/30/2019	3.2	
4.1		Form of the Registrant's Common Stock Certificate	8-K	3/18/2020	4.1	
4.2		Amended and Restated Investor Rights Agreement by and between the Registrant and certain holders of the Registrant's capital stock dated as of December 1, 2010	10-Q	5/10/2012	4.3	
10.1	†	PRV Transfer Agreement, dated as of July 27, 2020, by and between the Registrant and Merck, Sharp & Dohme Corp.				X
10.2	†	Amendment No. 1 as of August 12, 2020 to Lumos Merck Agreement with Merck				X
10.3	*	Employment Agreement, dated as of March 27, 2020, by and between the Registrant and Richard Hawkins	8-K	4/2/2020	10.1	
10.4	*	Employment Agreement, dated as of March 27, 2020, by and between the Registrant and John McKew	8-K	4/2/2020	10.2	
31.1		Certification of principal executive officer required by Rule 13a-14(a) / 15d-14(a)				X
31.2		Certification of principal financial officer required by Rule 13a-14(a) / 15d-14(a)				X
32.1	#	Section 1350 Certification				X
101.INS	‡	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	‡	XBRL Taxonomy Extension Schema Document				X
101.CAL	‡	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	‡	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	‡	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	‡	XBRL Taxonomy Extension Presentation Linkbase Document				X
104		Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				X

The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Lumos Pharma, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

‡ Filed herewith electronically.

* Indicates management contract or compensatory plan.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

LUMOS PHARMA, INC.

By: /s/ Richard J. Hawkins
Richard J. Hawkins
Chief Executive Officer
(Principal Executive Officer)
Date: August 14, 2020

By: /s/ Carl W. Langren
Carl W. Langren
Chief Financial Officer and Secretary
(Principal Financial Officer)
Date: August 14, 2020

Exhibit 10.1

ASSET PURCHASE AGREEMENT

BY AND BETWEEN

LUMOS PHARMA, INC.

AND

MERCK SHARP & DOHME CORP.

July 27, 2020

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (this "***Agreement***") is made and entered into as of July 27, 2020 (the "***Effective Date***"), by and between Merck Sharp & Dohme Corp. ("***Merck***") and Lumos Pharma, Inc. ("***Lumos***"). Merck and Lumos may hereinafter be referred to individually as a "***Party***" and collectively as the "***Parties***".

RECITALS

WHEREAS, BioProtection Systems Corporation, an Affiliate of Lumos and a wholly-owned subsidiary of Lumos, is the holder of all right, title and interest in and to the Priority Review Voucher (as defined below).

WHEREAS, Lumos and Merck each (i) desire that Merck purchase from BioProtection Systems Corporation, and BioProtection Systems Corporation sell, transfer and assign to Merck, the Purchased Assets (as defined below), all on the terms set forth herein (such transaction, the "***Asset Purchase***") and (ii), in furtherance thereof, have duly authorized, approved and executed this Agreement and the other transactions contemplated by this Agreement in accordance with all applicable Legal Requirements (as defined below).

WHEREAS, Lumos and Merck desire to make certain representations, warranties, covenants and other agreements in connection with the Asset Purchase as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and their mutual undertakings hereinafter set forth, and intending to be legally bound, the Parties hereto agree as follows:

ARTICLE 1. DEFINITIONS

1.1 Certain Definitions. As used in this Agreement, the following terms shall have the meanings indicated below:

(a) "***Affiliate***" means any Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. The term "control" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

(b) "***BLA Approval Letter***" means the BLA approval letter dated December 19, 2019 from the Department of Health and Human Services to Merck, Reference ID STN: BL 125690/0, approving the Subject BLA, issuing Department of Health and Human Services U.S. License No. 0002, and granting the Priority Review Voucher.

(c) "***Business Day***" means a day (i) other than Saturday or Sunday and (ii) on which commercial banks are open for business in New York, New York.

(d) "***Confidential Information***" means (i) any and all confidential and proprietary information, including data, results, conclusions, know-how, experience, financial information, plans

and forecasts, that may be delivered, made available, disclosed or communicated by a Party or its Affiliates or their respective Representatives to the other Party or its Affiliates or their respective Representatives, related to the subject matter hereof or otherwise in connection with this Agreement and (ii) the terms, conditions and existence of this Agreement. "*Confidential Information*" will not include information that (A) at the time of disclosure, is generally available to the public, (B) after disclosure hereunder, becomes generally available to the public, except as a result of a breach of this Agreement by the recipient of such information, (C) becomes available to the recipient of such information from a Third Party that is not legally or contractually prohibited by the disclosing Party from disclosing such Confidential Information, or (D) was developed by or for the recipient of such information without the use of or reference to any of the Confidential Information of the disclosing Party or its Affiliates, as evidenced by the recipient's contemporaneous written records.
Notwithstanding anything herein to the contrary, all Confidential Information included within the Purchased Assets shall constitute Confidential Information of Merck from and after the Closing Date.

(e) "***Contract***" means any written or oral legally binding contract, agreement, instrument, commitment or undertaking (including leases, licenses, mortgages, notes, guarantees, sublicenses, subcontracts and purchase orders).

(f) "***Encumbrance***" means any lien, pledge, charge, mortgage, easement, encroachment, imperfection of title, title exception, title defect, right of possession, right of negotiation or refusal, lease, security interest, encumbrance, adverse claim, interference or restriction on use or transfer.

(g) "***FDA***" means the United States Food and Drug Administration.

(h) "***FDA Notification Package***" means, collectively, executed versions of the joint FDA notification cover letter, Lumos and BioProtection Systems Corporation transfer acknowledgement letter and Merck transfer acknowledgement letter in the forms set forth in **Exhibits C-1**, **C-2**, and **C3**, respectively, and, with respect to such joint FDA notification cover letter as set forth in **Exhibit C-1**, any other documentation referred to therein as being attached thereto, in each case, with respect to the purchase and sale of the Priority Review Voucher pursuant to this Agreement to be submitted to the FDA jointly by Merck and Lumos or BioProtection Systems Corporation pursuant to Section 3.2(c).

(i) "***FDC Act***" means the Federal Food, Drug, and Cosmetic Act, 21 USC 301, *et seq*. as amended, and including any rules, regulations and requirements promulgated thereunder.

(j) "***Governmental Entity***" means any supranational, national, state, municipal, local or foreign government, any court, tribunal, arbitrator, administrative agency, commission or other governmental official, authority or instrumentality, in each case whether domestic or foreign, any stock exchange or similar self-regulatory organization or any quasi-governmental or private body exercising any regulatory, taxing or other governmental or quasi-governmental authority.

(k) "***HSR Act***" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and including any rules, regulations and requirements promulgated thereunder.

(l) "***Knowledge***" means, with respect to Lumos and its Affiliates, the actual knowledge of (a) the Chief Executive Officer, (b) the Chief Financial Officer, and (c) the General Counsel of Lumos, after performing a reasonable inquiry.

(m) "***Legal Requirements***" means any federal, state, foreign, local, municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Entity and any Orders applicable to a Party or to any of its assets, properties or businesses. Legal Requirements shall include, with respect to Lumos, any responsibilities, requirements, obligations, parameters and conditions relating to the Priority Review Voucher set forth in (i) the BLA Approval Letter, (ii) any other correspondence received by Lumos or its Affiliates from the FDA regarding the Priority Review Voucher, (iii) Section 529 of the FDC Act (21 USC 360ff), or (iv) the July 24, 2019 FDA draft guidance document, "Tropical Disease
Priority Review Vouchers, Guidance for Industry."

(n) "***Liabilities***" means all debts, liabilities and obligations, whether presently in existence or arising hereafter, accrued or fixed, absolute or contingent, matured or unmatured, determined or determinable, asserted or un asserted, known or unknown, including those arising under any law, action or Order and those arising under any Contract.

(o) "***License and Collaboration Agreement***" means the license and collaboration agreement, by and among Merck, BioProtection Systems Corporation and NewLink Genetics Corporation, effective as of November 21, 2014.

(p) "***Order***" means any order, decree, edict, injunction, writ, award or judgment of any Governmental Entity.

(q) "***Person***" means any natural person, company, corporation, limited liability company, general partnership, limited partnership, trust, proprietorship, joint venture, business organization or Governmental Entity.

(r) "***PHAC Agreement***" means the Amended and Restated License Agreement by and between BioProtection Systems Corporation, an Affiliate of Lumos, and Her Majesty the Queen in Right of Canada, as represented by the Minister of Health, acting through the Public Health Agency of Canada, dated December 5, 2017.

(s) "***Priority Review***" means review and action by the FDA on a human drug application in accordance with Section 529(a)(1) of the FDC Act.

(t) "***Priority Review Voucher***" means the priority review voucher issued by the United States Secretary of Health and Human Services to Merck, as the sponsor of a tropical disease product application, and assigned tracking number PRV BLA 125690, that entitles the holder of such voucher to Priority Review, as evidenced by a copy of the letter attached hereto as **Exhibit A**.

(u) "***Proceeding***" means any claim, action, arbitration, audit, hearing, investigation, litigation, proceeding or suit (whether civil, criminal, administrative, judicial or investigative, whether formal or informal, whether public or private) commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Entity or arbitrator.

"***Purchased Assets***" means (i) the Priority Review Voucher, and (ii) any and all rights, benefits and entitlements afforded to the holder of the Priority Review Voucher.

(v) "***Representative***" means, with respect to a particular Person, any director, officer, manager, employee, agent, consultant, advisor, accountant, financial advisor, legal counsel or other representative of that Person.

(w) "***Subject BLA***" means BLA No. 125690 approved on December 19, 2019, and the subject of Department of Health and Human Services U.S. License No. 0002, issued to Merck with respect to Ebola Zaire Vaccine, Live, which is indicated for the prevention of disease caused by Zaire ebolavirus in individuals 18 years of age and older.

(x) "***Third Party***" means any Person other than a Party and such Party's Affiliates.

Other capitalized terms defined elsewhere in this Agreement and not defined in this Section 1.1 shall have the meanings assigned to such terms in this Agreement.

ARTICLE 2. PURCHASE AND SALE

2.1 Purchase and Sale; No Assumed Liabilities.

(a) Upon the terms and subject to the conditions of this Agreement, Merck agrees to purchase from BioProtection Systems Corporation, and Lumos and BioProtection Systems Corporation agree to sell, transfer, convey, assign and deliver to Merck, at the Closing all of the Purchased Assets free and clear of all Encumbrances.

(b) Merck shall not assume or be liable for any Liabilities of Lumos, BioProtection Systems Corporation or its Affiliates (fixed, contingent or otherwise, and whether or not accrued) (such Liabilities, "***Excluded Liabilities***").

b. Purchase Price. The Parties agree that the value of the Purchased Assets is One Hundred Million United States Dollars (U.S. $100,000,000). Pursuant to the License and Collaboration Agreement, Merck is entitled to 40% of the value of the Purchased Assets. Accordingly, the total consideration to be paid by Merck for all of the Purchased Assets shall be Sixty Million United States Dollars (U.S. $60,000,000) (the "***Purchase Price***"). For clarity, upon the Closing, all of the payment obligations of Lumos or BioProtection Systems Corporation to Merck under Section 5.3.1 of the License and Collaboration Agreement shall be deemed to be satisfied.

c. Method of Payment. Merck shall pay the Purchase Price in two installments. The first installment of Thirty Four Million United States Dollars (U.S. $34,000,000) shall be due and payable at the Closing and the second installment of Twenty Six Million United States Dollars (U.S. $26,000,000) shall be due and payable on January 11, 2021. All payments to Lumos shall be made in cash by wire transfer of immediately available funds to a bank account specified by Lumos in writing to Merck in Schedule 2.3 of this Agreement

ARTICLE 3. CLOSING

3.1 Closing. The consummation of the transactions contemplated by this Agreement (the "***Closing***") shall be conducted telephonically and/or via email or other similar means of correspondence

on the third (3rd) Business Day after all of the conditions set forth in ARTICLE 6 have been satisfied or waived (other than those conditions, which, by their terms, are intended to be satisfied at the Closing, but subject to satisfaction or waiver of such condition) or such other date as may be mutually agreed upon in writing by Merck and Lumos. The date on which the Closing actually takes place is referred to in this Agreement as the "***Closing Date***".

3.2 Transactions to be Effected at Closing.

(a) At the Closing, Lumos on behalf of itself and BioProtection Systems Corporation, shall deliver, or cause to be delivered, to Merck:

a. The certificate referred to in Section 6.2(c), appropriately executed;

b. A duly executed Bill of Sale, in the form attached hereto as **Exhibit B** (the "***Bill of Sale***"); and

c. A copy of the joint FDA notification cover letter and the Lumos transfer acknowledgement letter for inclusion in the FDA Notification Package, which FDA cover letter and Lumos transfer acknowledgement letter shall be in the form of **Exhibit C-1** and **Exhibit C-2**, respectively, or such other form as the FDA may require as of the Closing Date.

(b) At the Closing, Merck shall deliver, or cause to be delivered, to Lumos:

i. The certificate referred to in Section 6.3(c), appropriately executed; ii. A duly executed Bill of Sale;

c. The first installment of the Purchase Price, by wire transfer of immediately available finds to the account specified in Schedule 2.3 of this Agreement; and

d. A copy of the joint FDA notification cover letter and the Merck transfer acknowledgement letter for inclusion in the FDA Notification Package, which FDA cover letter and Merck transfer acknowledgement letter shall be in the form attached hereto as **Exhibit C-1** and **Exhibit C-3**, respectively, or such other form as the FDA may require as of the Closing Date.

(c) On the Closing Date, Merck and Lumos shall submit the fully executed FDA Notification Package to the FDA.

3.3 Title Passage; Notification.

(a) Title Passage. Upon Closing, all of the right, title and interest of Lumos and its Affiliates, including BioProtection Systems Corporation, in and to the Purchased Assets shall pass to Merck.

(b) Filings; Notifications. Merck and Lumos agree to reasonably cooperate and assist each other with respect to all filings.

ARTICLE 4.
REPRESENTATIONS AND WARRANTIES OF LUMOS

Lumos represents and warrants to Merck, as of the Effective Date and as of the Closing Date, as follows:

4.1 Organization, Standing and Power. Lumos is a corporation duly organized and validly existing under the laws of the State of Delaware. Lumos has the corporate power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect any of the Purchased Assets or Lumos's ability to consummate the transactions contemplated by this Agreement. Lumos is not in violation of its certificate of incorporation or bylaws, in each case as amended to date. BioProtection Systems Corporation is an Affiliate and a wholly-owned subsidiary of Lumos.

4.2 Due Authority. Lumos has the requisite corporate power and authority to enter into and perform its obligations and the obligations of BioProtection Systems Corporation under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly approved and authorized by all necessary corporate action on the part of Lumos, and this Agreement has been duly executed and delivered by Lumos. This Agreement, upon execution by the Parties, will constitute a valid and binding obligation of Lumos enforceable against Lumos in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

4.3 Required Approval. No Third Party approval is necessary to approve the Asset Purchase.

4.4 Noncontravention. The execution and delivery of this Agreement by Lumos does not, and the consummation of the transactions contemplated hereby, including the transfer of title to, ownership in, and possession of the Purchased Assets, will not, (a) result in the creation of any Encumbrance on any of the Purchased Assets or (b) conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (i) any provision of the certificate of incorporation or bylaws of Lumos, in each case as amended to date, (ii) any Contract to which Lumos or any Affiliate of Lumos is a party or by which it or its assets are bound which involves or affects in any way any of the Purchased Assets or (iii) except as may be required to comply with the HSR Act (if applicable), any Legal Requirements applicable to Lumos or any Affiliate of Lumos or any of the Purchased Assets.

4.5 No Consents. Except for the FDA Notification Package, and, if applicable, the filing of a Premerger Notification and Report Form under the HSR Act, no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Lumos to enter into, and to perform its obligations under, this Agreement.

4.6 Title to Purchased Assets. BioProtection Systems Corporation, a wholly owned subsidiary of Lumos, is the sole and exclusive owner of the Purchased Assets and at the Closing will transfer to Merck good and transferable title to the Purchased Assets free and clear of any Encumbrances.

BioProtection Systems Corporation has performed all actions reasonably necessary to perfect its ownership of, and its ability to transfer, the Purchased Assets.

4.7 Contracts. Except for this Agreement and the License and Collaboration Agreement, there is no Contract to which Lumos or any Affiliate of Lumos is a party that involves or affects the ownership of, licensing of, title to, or use of any of the Purchased Assets.

4.8 Compliance With Legal Requirements. Lumos and its Affiliates are, and at all times have been, in full compliance with each Legal Requirement that is or was applicable to (a) Lumos's and its affiliates' conduct, acts, or omissions with respect to any of the Purchased Assets or (b) any of the Purchased Assets. Lumos and its Affiliates have not received any notice or other communication (whether oral or written) from any Person regarding actual, alleged, possible or potential violation of, or failure to comply with, any such Legal Requirement.

4.9 Legal Proceedings. Except as set forth in **Schedule A** attached hereto (the "***Lumos Disclosure Schedule***"), there is no pending, or to Lumos's Knowledge, threatened Proceeding that involves or affects (or may involve or affect) the ownership of, licensing of, title to, or use of any of the Purchased Assets. None of the Purchased Assets are subject to any Order of any Governmental Entity or arbitrator.

4.10 Governmental Authorizations. Lumos is not required to hold any license, registration, or permit issued by any Governmental Entity to own, use or transfer the Purchased Assets, other than such licenses, registrations or permits that have already been obtained.

4.11 Solvency. Lumos is not entering into this Agreement with the actual intent to hinder, delay, or defraud any creditor of Lumos. The remaining assets of Lumos after the Closing will not be unreasonably small in relation to the business in which Lumos will engage after the Closing. Upon and immediately following the Closing Date, after giving effect to all of the transactions contemplated by and in this Agreement (including the payment of the Purchase Price), Lumos will not be insolvent and will have sufficient capital to continue in business and pay its debts as they become due.

4.12 Revocation; Use of Purchased Assets. The Priority Review Voucher has not been terminated, cancelled or revoked, and neither Lumos nor any of its Affiliates or any of their respective Representatives has taken or omitted to take any action, and to Lumos's Knowledge there are no facts or circumstances that would reasonably be expected to (with or without notice or lapse of time or both) result in the termination, cancellation or revocation of the Priority Review Voucher. There is no term or condition imposed by the FDA on the Priority Review Voucher that is not set forth in the BLA Approval Letter or Section 524 of the FDC Act. Lumos has provided to Merck true and complete copies of the BLA Approval Letter and any other material communications received by Lumos or any of its Affiliates from the FDA regarding the Priority Review Voucher.

4.13 Intent to Use. Neither Lumos nor any of its Affiliates has notified the FDA of intent to use the Priority Review Voucher to obtain a Priority Review.

ARTICLE 5 REPRESENTATIONS AND WARRANTIES OF MERCK

Merck represents and warrants to Lumos as follows:

5.1 Organization, Standing and Power. Merck is a corporation duly organized and validly existing under the laws of the State of New Jersey. Merck has the corporate power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect any of the Purchased Assets or Merck's ability to consummate the transactions contemplated by this Agreement. Merck is not in violation of its certificate of incorporation or bylaws, in each case as amended to date.

5.2 Due Authority. Merck has the requisite corporate power and authority to enter into and perform its obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly approved and authorized by all necessary corporate action on the part of Merck, and this Agreement has been duly executed and delivered by Merck. This Agreement, upon execution by the Parties, will constitute a valid and binding obligation of Merck enforceable against Merck in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

5.3 Noncontravention. The execution and delivery of this Agreement by Merck does not, and the consummation of the transactions contemplated hereby will not, conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (a) any provision of the certificate of incorporation or bylaws of Merck, in each case as amended to date, (b) any Contract to which Merck or any Affiliate of Merck is bound, or (iii) except as may be required to comply with the HSR Act (if applicable), any Legal Requirements applicable to Merck or any Affiliate of Merck.

5.4 No Consents. Except for the FDA Notification Package and, if applicable, the filing of a Premerger Notification and Report Form under the HSR Act, no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Merck to enter into, and to perform its obligations under, this Agreement.

ARTICLE 6. CONDITIONS TO CLOSING

6.1 Conditions Precedent of Merck and Lumos. Each Party's obligations to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) HSR Act. If applicable, the waiting period under the HSR Act relating to the transactions contemplated by this Agreement shall have expired.

(b) No Injunctions or Restraints. No temporary restraining order, preliminary or permanent injunction or other material legal restraint or prohibition issued or promulgated by a Governmental Entity preventing the consummation of the transactions contemplated by this Agreement shall be in effect, and there shall not be any applicable Legal Requirement that makes consummation of the transactions contemplated by this Agreement illegal.

(c) No Governmental Litigation. There shall not be any Proceeding commenced or pending by a Governmental Entity seeking to prohibit, limit, delay, or otherwise restrain the consummation of this Agreement and/or the transactions contemplated hereby.

6.2 Merck's Conditions Precedent. The obligations of Merck to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) Accuracy of Representations. Each of the representations and warranties made by Lumos in this Agreement (other than the representations and warranties made by Lumos in Sections 4.1, 4.2, 4.6, 4.9, 4.11, 4.12 and 4.13) shall be true and correct in all respects at and as of the Closing Date (or, if made as of a specified period or date, as of such period or date), *provided* that any such failure of such representations and warranties to be true and correct shall be disregarded if it would not, individually or in the aggregate, reasonably be expected to restrict, limit or preclude the transfer and/or use of the Purchased Assets to or by Merck. Each of the representations and warranties made by Lumos in Sections 4.1, 4.2, 4.6, 4.9, 4.11, 4.12 and 4.13 shall be true and correct in all respects at and as of the Closing Date (or, in each case, if made as of a specified period date, as of such period or date).

(b) Performance of Covenants. All of the covenants and obligations that Lumos is required to comply with or to perform hereunder at or prior to the Closing Date shall have been complied with and performed in all material respects.

(c) Closing Certificate. Lumos shall have delivered to Merck a certificate, dated the Closing Date and signed by Lumos, certifying that the conditions set forth in Sections 6.2(a) and 6.2(b) have been satisfied.

6.3 Lumos's Conditions Precedent. The obligations of Lumos to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, or each of the following conditions precedent:

(a) Accuracy of Representations. Each of the representations and warranties made by Merck in this Agreement shall be true and correct in all respects at and as of the Closing Date (or, if made as of a specified period or date, as of such period or date), except to the extent that such representations and warranties are qualified by the term "material", or words of similar import, in which case such representations and warranties (as so written, including the terms "material", or words of similar import) shall be true and correct in all respects at and as of the Closing Date (or, if made as of a specified period or date, as of such period or date).

(b) Performance of Covenants. All of the covenants and obligations that Merck is required to comply with or to perform hereunder at or prior to the Closing Date shall have been complied with and performed in all material respects.

(c) Closing Certificate. Merck shall have delivered to Lumos a certificate, dated the Closing Date and signed by Merck, certifying that the conditions set forth in Sections 6.3(a) and 6.3(b) have been satisfied.

ARTICLE 7 PRE-CLOSING COVENANTS AND AGREEMENTS

7.1 Antitrust Notification.

(a) If a filing under the HSR Act is required, Lumos and Merck shall file, or shall cause their ultimate parent entities as defined in the HSR Act to file, as soon as practicable (but not later than ten (10) Business Days) after the Effective Date, any notifications required under the HSR Act, and shall respond as promptly as practicable to all inquiries or requests received from the Federal Trade Commission, the Antitrust Division of the Department of Justice or any Governmental Entity for additional information or documentation. Each Party shall pay for the fees associated with their own filings and submissions. In connection therewith, the Parties shall, or shall cause their respective Affiliates to, (i) furnish to the other Party such necessary information and reasonable assistance as the other Party may reasonably request in connection with its preparation of any filing or submission that is necessary under the HSR Act, and (ii) keep the other Party reasonably apprised of the status of any communications with, and any inquiries or requests for additional information from the applicable Governmental Entity.

(b) Subject to applicable confidentiality restrictions or restrictions required by applicable Legal Requirements, each Party will notify the other promptly upon the receipt of (i) any comments or questions from any Governmental Entity in connection with any filings made pursuant to Section 7.1(a) or the transactions contemplated by this Agreement and (ii) any requests by any Governmental Entity for information or documents relating to an investigation of the transactions contemplated by this Agreement. Without limiting the generality of the foregoing, each Party shall provide to the other (or the other's respective advisors) upon request copies of all correspondence between such Party and any Governmental Entity relating to the transactions contemplated by this Agreement. The Parties may, as they deem advisable and necessary, designate any correspondence provided to the other under this Section 7.1(b) as "outside counsel only." Such materials and the information contained therein shall be given only to outside counsel of the recipient and will not be disclosed by such outside counsel to employees, officers, or directors of the recipient without the advance written consent of the Party providing such materials. In addition, to the extent reasonably practicable, all discussions, telephone calls, and meetings with a Governmental Entity regarding the transactions contemplated by this Agreement shall include representatives of both Parties. Subject to applicable Legal Requirements, the Parties will consult and cooperate with each other in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, and proposals made or submitted to any Governmental Entity regarding the transactions contemplated by this Agreement by or on behalf of any Party.

ARTICLE 8. INDEMNIFICATION

8.1 Indemnification.

(a) Indemnification by Lumos. From and after the Closing, Lumos will indemnify defend and hold Merck and its Affiliates, and their respective directors, officers, employees and agents harmless for, from and against any and all Liabilities, losses, damages, costs and expenses (including reasonable attorneys' fees) (collectively, "***Damages***") to the extent arising out of or resulting from (i) any breach of Lumos's representations, warranties, covenants or obligations under this Agreement or any certificate delivered by Lumos hereunder, (ii) Lumos's grossly negligent and/or wrongful acts,

omissions or misrepresentations, regardless of the form of action, in connection with this Agreement, and/or (iii) any Excluded Liabilities.

(b) Indemnification by Merck. From and after the Closing, Merck will indemnify defend and hold Lumos and its Affiliates, and their respective directors, officers, employees and agents harmless for, from and against any and all Damages to the extent arising out of or resulting from (i) any breach of Merck's representations, warranties, covenants or obligations under this Agreement or any certificate delivered by Merck hereunder, (ii) Merck's grossly negligent and/or wrongful acts, omissions or misrepresentations, regardless of the form of action, in connection with this Agreement, and/or (iii) Merck's, its Affiliates', or any subsequent transferee's use or ownership of the Purchased Assets.

8.2 Indemnification Procedures for Third Party Claims.

(a) A Person entitled to indemnification pursuant to Section 8.1 will hereinafter be referred to as an "***Indemnitee***." A Party obligated to indemnify an Indemnitee hereunder will hereinafter be referred to as an "***Indemnitor***." Indemnitee shall inform Indemnitor of any indemnifiable Damages arising out of a third party in respect of which an Indemnitee may seek indemnification pursuant to Section 8.1 (a "***Third Party Claim***") as soon as reasonably practicable after the Third Party Claims arises, it being understood and agreed that the failure to give such notice will not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that such Indemnitor is actually and materially prejudiced as a result of such failure to give notice.

(b) If the Indemnitor has acknowledged in writing to the Indemnitee within thirty (30) days of receipt of the Third Party Claim the Indemnitor's responsibility for defending such Third Party Claim, the Indemnitor shall have the right to defend at its sole cost and expense, such Third Party
Claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnitor to a final conclusion or settled at the discretion of the Indemnitor; provided, however, that the Indemnitor may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnitee of a release from all liability in respect of such Third Party Claim; and (ii) the Indemnitee consents to such compromise or settlement, which consent shall not be withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnitee, (B) any payment by the Indemnitee that is not indemnified hereunder, or (C) the imposition of any equitable relief against the Indemnitee. If the Indemnitor does not elect to assume control of the defense of a Third Party Claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnitor, the Indemnitee shall have the right, at the expense of the Indemnitor, upon at least ten (10) Business Days' prior written notice to the Indemnitor of its intent to do so, to undertake the defense of such Third Party Claim for the account of the Indemnitor (with counsel reasonably selected by the Indemnitee and approved by the Indemnitor, such approval not to be unreasonably withheld or delayed), provided, that the Indemnitee shall keep the Indemnitor apprised of all material developments with respect to such Third Party Claim and promptly provide the Indemnitor with copies of all correspondence and documents exchanged by the Indemnitee and the opposing party(ies) to such litigation. The Indemnitee may not compromise or settle such litigation without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld or delayed.

(c) The Indemnitee may participate in, but not control, any defense or settlement of any Third Party Claim controlled by the Indemnitor pursuant to this Section 8.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnitor shall bear such costs and expenses if counsel for the Indemnitor shall have reasonably determined that such counsel may not properly represent both the Indemnitor and the Indemnitee.

8.3 Direct Claims. A claim for indemnification for any matter not involving a Third Party Claim may be asserted by written notice to the Party from whom indemnification is sought. Such notice shall include the facts constituting the bases for such claim for indemnification, the Sections of this Agreement upon which such claim for indemnification is then based, and an estimate, if possible, of the amount of Damages suffered or reasonably expected to be suffered by the party seeking indemnification.

ARTICLE 9. TERMINATION

9.1 Termination Prior to Closing. Notwithstanding any contrary provisions of this Agreement, the respective obligations of the Parties hereto to consummate the transactions contemplated by this Agreement may be terminated and abandoned at any time before Closing only as follows:

(a) Upon the mutual written consent of Merck and Lumos; or

(b) By either Party, by written notice to the other Party if the Closing has not occurred on or before one hundred and thirty-five (135) days from the Effective Date for any reason; provided, however, that the right to terminate this Agreement under this Section 9.1(b) shall not be available to any Party whose material breach of any provision set forth in this Agreement has resulted in the failure of the Closing to occur on or before such date.

9.2 Effect of Termination. In the event of the termination of this Agreement as provided in Section 9.1, written notice thereof shall forthwith be given to the other Party hereto specifying the provision hereof pursuant to which such termination is made, and this Agreement shall forthwith become null and void (except for the provisions of this Section 9.2, Section 10.3, ARTICLE 1, ARTICLE 8 and ARTICLE 11, which shall survive any such termination) and there shall be no liability on the part of Merck or Lumos except for damages resulting from any breach prior to termination of this Agreement by Merck or Lumos.

ARTICLE 10. ADDITIONAL COVENANTS

10.1 Further Assurances.

(a) The Parties shall cooperate reasonably with each other in connection with any steps required to be taken as part of their respective obligations under this Agreement, including any notifications or filings required to be made to the FDA in connection with the transfer of the Purchased Assets, and shall (a) furnish upon request to each other such information, (b) execute and deliver to each other such other documents, and (c) do such other acts and things, all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement and the transactions contemplated by this Agreement, including the use by Merck, its Affiliates and/or their respective successors and assigns of the Priority Review Voucher in accordance with its terms and applicable Legal Requirements.

(b) Without limiting the foregoing, Merck and Lumos agree to cooperate and assist each other with respect to all filings or notifications to any Governmental Entity related to the transfer and assignment of the Purchased Assets.

(b) Compliance with Legal Requirements. Lumos shall, and shall cause its Affiliates and each of their respective successors in interest to the tropical disease product for which the Priority Review Voucher was awarded to, at all times comply with all Legal Requirements applicable to the Purchased Assets, including any and all Legal Requirements applicable to the use or transfer of the Priority Review Voucher. Lumos shall promptly forward to Merck any communications or notices related to the Purchased Assets sent from any Governmental Entity that Lumos or its Affiliates receive.

(c) Nondisclosure.

(a) With respect to Confidential Information received from a Party, the other Party will (i) not use such Confidential Information for any reason other than to carry out the intent and purpose of this Agreement, and (ii) not disclose such Confidential Information to any Person, except in each case as otherwise expressly permitted by this Agreement or with the prior written consent of the disclosing Party.

(b) A Party may disclose Confidential Information to its Affiliates and their respective Representatives on a need-to-know basis.

(c) A Party will (i) enforce the terms of this Section 10.3 as to its Representatives, (ii) take such action to the extent necessary to cause its Representatives to comply with the terms and conditions of this Section 10.3, and (iii) be responsible for any breach of this Section 10.3 by it or its Representatives.

(d) If a Party becomes compelled by a judicial or administrative process (including a request for discovery received in an arbitration or litigation proceeding) to make any disclosure that is prohibited or otherwise constrained by this Section 10.3, such Party shall provide the other Party with prompt notice of such compulsion so that the other Party has an opportunity to seek an appropriate protective order or other appropriate remedy or waive compliance with the provisions of this Section 10.3. In the absence of a protective order or other remedy, the Party subject to the requirement to disclose may disclose that portion (and only that portion) of the Confidential Information that, based upon advice of its counsel, it is legally compelled to disclose; provided, however, that such Party shall use reasonable efforts to obtain reliable assurance that confidential treatment will be accorded by any Person to whom any Confidential Information is so disclosed.

10.4 Disclosures Concerning this Agreement. Merck and Lumos have mutually agreed that Lumos may issue a press release on or after the Effective Date with respect to the execution of this Agreement in the form attached as **Exhibit D** hereto. Merck and Lumos agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Entity or applicable Legal Requirement (including the rules and regulations of any stock exchange or trading market on which a Party's securities are traded); provided that the Party intending to disclose such information shall: (a) use reasonable efforts to provide the other Party with advance notice of such required disclosure, and an opportunity to review and comment on such proposed disclosure, and (b) in good faith consider incorporating such comments and

use reasonable efforts to incorporate such comments, limit the proposed disclosure or obtain confidential treatment of such proposed disclosure to the extent reasonably requested by the other Party (which comments shall be considered in good faith by the disclosing Party). Each Party acknowledges that the other Party, or the other Party's parent entity, as a publicly traded company, is legally obligated to make timely disclosures of material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange

Commission (the "***SEC***"). Without limiting the foregoing, any Party so obligated shall provide the other Party with a reasonable opportunity to review, comment and request confidential treatment of this Agreement pursuant to applicable rules under the Securities Exchange Act of 1934, as amended, and the Freedom of Information Act and the rules promulgated thereunder to permit the filing of a redacted exhibit. The Party so obligated shall (a) give due consideration to the other Party's request, and (b) use reasonable efforts to incorporate any comments provided by the other Party, limit such disclosure or obtain such confidential treatment or permission to redact such exhibit, provided that there is no assurance that such request will be granted by the SEC and the SEC may require filing of the Agreement in full. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement.

ARTICLE 11. GENERAL PROVISIONS

11.1 Survival. Except as expressly set forth herein, the representations and warranties contained in this Agreement, and liability for the breach thereof, shall survive the Closing Date and shall remain in full force and effect for a period of three (3) years following the Closing Date; provided, however, that the representations and warranties contained in Sections 4.1, 4.2, 4.6, 4.9, 4.11, 4.12 and 4.13 hereof, and all covenants and obligations contained herein, shall, in each case, survive the Closing Date and remain in full force and effect until the expiration of the applicable statute of limitations.

11.2 Transfer, Taxes, and Fees. Notwithstanding any provision in this Agreement to the contrary, each respective Party shall bear and pay any and all sales taxes, value added taxes, stamp taxes, use taxes, transfer taxes, documentary charges, recording fees or similar taxes, charges, or fees (including any penalties, interest and additions thereto) that may become payable by it or its Affiliates in connection with the Asset Purchase. For clarity, the obligation to withhold shall not be deemed "payable" by a Party or its Affiliates pursuant to the foregoing sentence, but shall be considered an obligation of the Party on whose behalf the withholding is paid to the Governmental Entity.

11.3 Priority Review Fee. The priority review fee described in Section 524(c) of the FDC Act (21 U.S.C § 360n) (the "***Priority Review Fee***") and all other user fees under the FDC Act applicable to human drug application for which the Priority Review Voucher is redeemed, following the Closing shall be borne exclusively by Merck, its Affiliates or any transferee of the Priority Review Voucher. In any event, Lumos shall have no liability or obligation for any such fees.

11.4 Notices. Any notice or other communication required or permitted to be delivered to any Party shall be in writing and shall be deemed properly delivered, given and received: (a) when delivered by hand; or (b) upon such Party's receipt after being sent by registered mail, by courier or express delivery service, in any case to the address set forth beneath the name of such Party below (or to such address as such Party shall have specified in a written notice given to the other Party in accordance with this Section 11.4):

if to Merck, to:
Merck Sharp & Dohme Corp.
One Merck Drive
PO Box 100
Whitehouse Station, NJ 08889-0100
Attention: Office of Secretary
Email: office.secretary@merck.com

With a copy (which shall not constitute notice) to:
Merck Sharp & Dohme Corp.
2000 Galloping Hill Drive
PO Box 539
Kenilworth, NJ 07033-1310
Attention: Senior Vice President, Business Development

if to Lumos, to:
Lumos Pharma, Inc.
2503 South Loop Drive, Suite 5100
Ames, IA 50010
Attention: General Counsel
Email: bpowers@lumos-pharma.com
With a copy (which shall not constitute notice) to:
Lumos Pharma, Inc.
4200 Marathon Blvd., Suite 200 Austin, Texas 78756

11.5 Construction.

i. The Parties agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement.

ii. As used in this Agreement, the words “include” and “including,” and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation.”

iii. Except as otherwise indicated, all references in this Agreement to “Articles” and “Sections” are intended to refer to Articles and Sections of this Agreement.

11.6 Counterparts. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same instrument, and shall become effective when one or more counterparts have been signed by each of the Parties hereto and delivered to the other Party hereto, it being understood that all Parties hereto need not sign the same counterpart. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic transmission or facsimile shall be sufficient to bind the Parties hereto to the terms and conditions of this Agreement.

11.7 Entire Agreement. This Agreement, including all exhibits and schedules attached hereto, set forth the entire understanding of the Parties relating to the purchase of the Purchased Assets and supersede all prior agreements and understandings among or between the Parties relating to thereto. For clarity, no provision in this Agreement shall supersede any provision of the License and Collaboration Agreement and shall not release Merck, Lumos or BioProtection Systems Corporation of any of their respective obligations or liabilities pursuant to the License and Collaboration Agreement. In the event of any inconsistencies between the terms of this Agreement and the License and Collaboration Agreement, the terms of the License and Collaboration Agreement will control. For clarity, the Parties agreement that all of the payment obligations of Lumos or BioProtection Systems Corporation to Merck under Section 5.3.1 of the License and Collaboration Agreement shall be deemed to be satisfied upon Closing pursuant to Section 2.2 shall not be deemed an inconsistency between the terms of this Agreement and the License and Collaboration Agreement.

11.8 Assignment. No Party will have the right to assign this Agreement, in whole or in part, by operation of law or otherwise, without the other Party's express prior written consent. Any attempt to assign this Agreement without such consent, will be null and void. Notwithstanding the foregoing, any Party may assign this Agreement, in whole or in part, without the consent of the other Party: (a) to a Third Party that succeeds to all or substantially all of its assets or business related to this Agreement (whether by sale, merger, operation of law or otherwise); or (b) to an Affiliate of such Party. Notwithstanding the foregoing, Merck may assign this Agreement, in whole or in part, without Lumos's consent, to any purchaser, transferee, or assignee of any of the Purchased Assets. For the avoidance of doubt, no assignment made pursuant to this Section 11.8 shall relieve the assigning Party of any of its obligations under this Agreement. Subject to the foregoing, this Agreement will bind and inure to the benefit of each Party's successors and permitted assigns.

11.9 Severability. If any provision of this Agreement, or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and shall be interpreted so as to reasonably effect the intent of the Parties hereto. The Parties hereto shall use commercially reasonable efforts to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such voided or unenforceable provision.

11.10 Remedies Cumulative. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party hereto shall be deemed cumulative with and not exclusive of any other remedy conferred hereby or by law or equity upon such Party, and the exercise by a Party hereto of any one remedy shall not preclude the exercise of any other remedy and nothing in this Agreement shall be deemed a waiver by any Party of any right to specific performance or injunctive relief.

11.11 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, regardless of the laws that might otherwise govern under applicable principles of conflicts of law. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court in Wilmington, Delaware (or if such court does not have subject matter jurisdiction, a State Court of the State of Delaware located in Wilmington, Delaware) solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

11.12 Amendment; Extension; Waiver. Subject to the provisions of applicable law, the Parties hereto may amend this Agreement at any time pursuant to an instrument in writing signed on behalf of each of the Parties hereto. At any time, any Party hereto may, to the extent legally allowed, (a) extend the time for the performance of any of the obligations or other acts of the other Party hereto, (b) waive any inaccuracies in the representations and warranties made to such Party contained herein or (c) waive compliance with any of the agreements or conditions for the benefit of such Party contained herein. Any agreement on the part of a Party hereto to any such extension or waiver shall be valid only if set forth in an instrument in writing signed on behalf of such Party. Without limiting the generality or effect of the preceding sentence, no delay in exercising any right under this Agreement shall constitute a waiver of such right, and no waiver of any breach or default shall be deemed a waiver of any other breach or default of the same or any other provision in this Agreement.

11.13 Representation By Counsel; Interpretation. Lumos and Merck each acknowledge that it has been represented by its own legal counsel in connection with this Agreement and the transactions contemplated by this Agreement. Accordingly, any rule of law, or any legal decision that would require interpretation of any claimed ambiguities in this Agreement against the Party that drafted it, has no application and is expressly waived.

11.14 Expenses. Whether or not the purchase and sale of the Purchased Assets and the other transactions contemplated by this Agreement are consummated, and expect as otherwise set forth in this Agreement, each of the Parties shall bear its own fees and expenses incurred in connection with this Agreement and the transactions contemplated hereby.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, each of Merck and Lumos has caused this Asset Purchase Agreement to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

MERCK SHARP & DOHME CORP.

By:

Name:

Title:

LUMOS PHARMA, INC.

By:

Name:

Title:

Exhibit A

Priority Review Voucher Letter

Our STN: BL 125690/0 **BLA APPROVAL**

December 19, 2019

Merck Sharp & Dohme Corp.
Attention: Jayanthi Wolf, PhD
351 N. Sumneytown Pike
P.O. Box 1000
UG2D-068
North Wales, PA 19454

Dear Dr. Wolf:

Please refer to your Biologics License Application (BLA) submitted on July 12, 2019, and received on July 15, 2019, under section 351(a) of the Public Health Service Act (PHS Act) for Ebola Zaire Vaccine, Live.

LICENSING

We have approved your BLA for Ebola Zaire Vaccine, Live effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Ebola Zaire Vaccine, Live under your existing Department of Health and Human Services U.S. License No. 0002. Ebola Zaire Vaccine, Live is indicated for the prevention of disease caused by *Zaire ebolavirus* in individuals 18 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT02269423, NCT02280408, NCT02374385, NCT02314923, NCT02287480, NCT02283099, NCT02296983, NCT02344407, NCT02378753, NCT02503202.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture Ebola Zaire Vaccine, Live at your facility located at Burgwedel, Germany. You may label your product with the proprietary name ERVEBO and market it in 1 mL single-dose vials.

We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for Ebola Zaire Vaccine, Live shall be 36 months from the date of manufacture when stored at -70±10°C. The date of manufacture shall be defined as the date of formulation of the Final Bulk Drug Product. The dating period for your drug substance shall be 36 months when stored at -70±10°C. We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of Ebola Zaire Vaccine, Live, or in the manufacturing facilities.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft package insert and the draft patient package insert labeling submitted under amendment 61, dated December 19, 2019, the draft carton labeling submitted under amendment 54, dated December 6, 2019, and draft container labeling submitted under amendment 50, dated November 22, 2019.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guida nces/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

PACKAGE AND CONTAINER LABELS

Please electronically submit final printed package and container labels that are identical to the package and container labels submitted on December 6, 2019, and November 22, 2019, respectively according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidan ces/ucm333969.pdf.

All final labeling should be submitted as Product Correspondence to this BLA 125690 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providingsubmissions-electronic-format-postmarketing-safety-reports-vaccines. For information on distribution reporting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation /Post-MarketActivities/LotReleases/ucm061966.htm.

TROPICAL DISEASE PRIORITY REVIEW VOUCHER

We also inform you that you have been granted a tropical disease priority review voucher (PRV), as provided under section 524 of the FDCA. This PRV has been assigned a tracking number, PRV BLA 125690. All correspondences related to this voucher should refer to this tracking number.

This voucher entitles you to designate a single human drug application submitted under section 505(b)(1) of the FDCA or a single biologic application submitted under section 351 of the Public Health Service Act as qualifying for a priority review. Such an application would not have to meet any other requirements for a priority review. The list below describes the sponsor responsibilities and the parameters for using and transferring a tropical disease PRV.

- The sponsor who redeems the PRV must notify FDA of its intent to submit an application with a PRV at least 90 days before submission of the application and must include the date the sponsor intends to submit the application. This notification should be prominently marked, "**Notification of Intent to Submit an Application with a Tropical Disease Priority Review Voucher**."

- This PRV may be transferred, including by sale, by you to another sponsor of a human drug or biologic application. If the PRV is transferred, the sponsor to

whom the PRV has been transferred should include a copy of this letter (which will be posted on our website as are all approval letters) and proof that the PRV was transferred. When redeeming this PRV, you should refer to this letter as an official record of the voucher.

For additional information regarding the PRV, see FDA's guidance, *Tropical Disease Priority Review Vouchers,* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guida nces/UCM080599.pdf.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 through 11 months because necessary studies are impossible or highly impracticable.

We are deferring submission of your pediatric study for ages 12 months through 16 years of age for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) is a required postmarketing study. The status of this postmarketing study must be reported according to 21 CFR 601.28 and section 505B(a)(4)(c) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an "**Annual Status Report of Postmarketing Study Requirement/Commitments**" and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. This required study is listed below:

1. Deferred study V920-016 to evaluate the safety and immunogenicity of ERVEBO in children 12 months through 17 years of age.

   Final Protocol Submission: October 21, 2016

   Study Completion: January 31, 2020

   Final Report Submission: June 30, 2021

Submit final study reports to this BLA 125690. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated as: **"Required Pediatric Assessment."**

POSTMARKETING COMMITMENT NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitment as described in your letter of December 17, 2019, as outlined below:

2. To provide the Final Drug Product process performance qualification final validation report as a "Postmarketing Commitment – Final Study Report."

   Final Report Submission: May 29, 2020

We request that you submit information concerning nonclinical and chemistry, manufacturing, and control postmarketing commitments and final reports to your BLA 125690. Please refer to the sequential number for each commitment.

Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Status Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing commitment not subject to the reporting requirements of 21 CFR 601.70, you may report the status to FDA as a **Postmarketing Commitment – Status Update**. The status report for each commitment should include:

- the sequential number for each study as shown in this letter;
- the submission number associated with this letter;
- describe what has been accomplished to fulfill the non-section 506B PMC; and,
- summarize any data collected or issues with fulfilling the non-section 506B PMC.

When you have fulfilled your commitment, submit your final report as **Postmarketing Commitment – Final Study Report** or **Supplement contains Postmarketing Commitment – Final Study Report**.

MEDWATCH-TO-MANUFACTURER PROGRAM

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biological products qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the

program, please see the enrollment instructions and program description details at http://www.fda.gov/Safety/MedWatch/HowToReport/ucm166910.htm.

REFERENCE PRODUCT DESIGNATION AND REQUEST FOR EXCLUSIVITY

We acknowledge your request for a date of first licensure (reference product exclusivity) as described under section 351(k)(7) of the PHS Act for Ebola Zaire Vaccine, Live. We are reviewing the relevant information including the information you provided and will notify you of our decision post approval.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

Sincerely,

/s/Marion F. Gruber

Marion F. Gruber, PhD
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research

Exhibit B

Form of Bill of Sale

This Bill of Sale (this "***Bill of Sale***") is entered into as of _____, 2020, by and between Merck Sharp & Dohme Corp. ("***Merck***") and Lumos Pharma, Inc. ("***Lumos***").

Upon the terms and subject to the conditions of the Asset Purchase Agreement, dated as of July 27, 2020 (the "***Asset Purchase Agreement***"), by and between Merck and Lumos, Lumos has agreed to sell, and Merck has agreed to purchase, all right, title and interest, in to and under the Purchased Assets, including the Priority Review Voucher, in each case free and clear of all Encumbrances.

For good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Merck and Lumos, intending to be legally bound, hereby agree as follows:

1. Defined Terms; Interpretation. Except as otherwise set forth herein, capitalized terms used in this Bill of Sale shall have the meanings assigned to them in the Asset Purchase Agreement. This Bill of Sale shall be interpreted in accordance with the rules of construction set forth in Section 11.5 of the Asset Purchase Agreement.

2. Transfer of Transferred Rights. Pursuant to the terms and subject to the conditions of the Asset Purchase Agreement, Lumos hereby sells, assigns, transfers, and conveys to Merck and its successors and its assigns, and Merck hereby does purchase from Lumos, all of Lumos's right, title and interest in, to and under the Purchased Assets, in each case free and clear of all Encumbrances. The right, title and interest in and to the Purchased Assets that are sold, transferred, conveyed, assigned and delivered by Lumos to Merck hereunder collectively constitute the entire right, title and interest in and to the Purchased Assets and upon the Closing, Merck shall have all right, title and interest in and to the Purchased Assets, free and clear of all Encumbrances.

3. Effective Time. This Bill of Sale shall be effective as of the Closing.

4. Conflicts. In the event of any conflict between the terms of the Bill of Sale and the Asset Purchase Agreement, the Asset Purchase Agreement shall control.

5. Binding Effect. This Bill of Sale shall be binding upon, inure to the benefit for of, and be enforceable by, the Parties hereto and their respective legal representatives, successors and permitted assigns.

6. Amendment. Subject to the provisions of applicable law, the Parties hereto may amend this Agreement at any time pursuant to an instrument in writing signed on behalf of each of the Parties hereto.

7. Governing Law. This Bill of Sale and any disputes arising under or related hereto shall be governed by the rules set forth in Section 11.11 of the Asset Purchase Agreement.

8. Counterparts. This Bill of Sale may be executed in two or more counterparts, all of which shall be considered one and the same instrument, and shall become effective when one or more counterparts have been signed by each of the Parties hereto and delivered to the other Party hereto, it being understood that all Parties hereto need not sign the same counterpart. The exchange of a fully

executed Bill of Sale (in counterparts or otherwise) by electronic transmission or facsimile shall be sufficient to bind the Parties hereto to the terms and conditions of this Bill of Sale.

[*Signature Page Follows]*

IN WITNESS WHEREOF, each of Merck and Lumos has caused this Asset Purchase Agreement to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

MERCK SHARP & DOHME CORP.

By: _____

Name: _____

Title: _____

LUMOS PHARMA, INC.

By: _____

Name: _____

Title: _____

Exhibit C-1

Form of Joint FDA Notification Cover Letter

_____, 2020

Marion F. Gruber, Ph.D. Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
U.S Food and Drug Administration Document Control Center

Re: BLA 125690
ERVEBO® (Ebola Zaire Vaccine, Live)
Transfer of Tropical Disease Priority Review Voucher PRV BLA 125690 **Joint FDA Notification Cover Letter**

Dear Dr. Gruber:

Reference is made to the December 19, 2019 letter approving the above-referenced BLA issued by the U.S. Food and Drug Administration (FDA) to Merck Sharp & Dohme Corp. (Merck), which granted Merck the above-referenced tropical disease priority review voucher (the Voucher).

Reference also is made to the General Correspondence and accompanying attachments, submitted to BLA 125690 on February 4, 2020, informing the FDA of the transfer of the Voucher from Merck to BioProtection Systems Corporation, then a wholly owned subsidiary of NewLink Genetics Corporation.

BioProtection Systems Corporation is now a wholly owned subsidiary of Lumos Pharma, Inc. (“Lumos”).

Pursuant to the terms set forth in an Asset Purchase Agreement between Lumos and Merck, dated July 27, 2020, BioProtection Systems Corporation has transferred, assigned, and conveyed the Voucher back to Merck and Merck has legally accepted complete ownership of the Voucher.

BioProtection Systems Corporation, Lumos, and Merck have exchanged letters acknowledging the transfer, copies of which are enclosed hereto.

Sincerely,

BioProtection Systems Corporations

By: _____

Name: _____

Title: _____

Lumos Pharma, Inc.

By: _____

Name: _____

Title: _____

Merck Sharp & Dohme Corp.

By: _____

Name: _____

Title: _____

Exhibit C-2

Form of Lumos Transfer Acknowledgement Letter

_____, 2020

Marion F. Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
U.S Food and Drug Administration Document Control Center

Re: BLA 125690
ERVEBO® (Ebola Zaire Vaccine, Live)
Transfer of Tropical Disease Priority Review Voucher PRV BLA 125690
Acknowledgement of Transfer Letter from BioProtection Systems Corporation and Lumos Pharma, Inc.

Dear Dr. Gruber:

Reference is made to the December 19, 2019 letter approving the above-referenced BLA issued by the U.S. Food and Drug Administration (FDA) to Merck Sharp & Dohme Corp. (Merck), which granted Merck the above-referenced tropical disease priority review voucher (the Voucher).

Reference also is made to the General Correspondence and accompanying attachments, submitted to BLA 125690 on February 4, 2020, informing the FDA of the transfer of the Voucher from Merck to BioProtection Systems Corporation, then a wholly owned subsidiary of NewLink Genetics Corporation.

In accordance with section 524(b)(2) of the Federal Food, Drug, and Cosmetic Act, please be advised that pursuant to the terms set forth in an Asset Purchase Agreement between Lumos Pharma, Inc. (“Lumos”) and Merck, dated July 27, 2020, BioProtection Systems Corporation has transferred the Voucher back to Merck. Specifically, BioProtection Systems Corporation has transferred, assigned, and conveyed the Voucher back to Merck and Merck has legally accepted complete ownership of the Voucher. This sale is free and clear of all liens and provides Merck with all of BioProtection Systems Corporation and Lumos’s rights, title, and interest in, to, and under the Voucher. This letter is the notification of transfer and acknowledgement from BioProtection Systems Corporation and Lumos.

Sincerely,

BioProtection Systems Corporation

By: _____

Name: _____

Title: _____ **Lumos Pharma, Inc.**

By: _____

Name: _____

Title: _____

Exhibit C-3

Form of Merck Transfer Acknowledgement Letter

_____, 2020

Marion F. Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
U.S Food and Drug Administration Document Control Center

Re: BLA 125690
ERVEBO® (Ebola Zaire Vaccine, Live)
Transfer of Tropical Disease Priority Review Voucher PRV BLA 125690
Acknowledgement of Transfer Letter from Merck Sharp & Dohme Corp.

Dear Dr. Gruber:

Reference is made to the December 19, 2019 letter approving the above-referenced BLA issued by the U.S. Food and Drug Administration to Merck Sharp & Dohme Corp. (Merck), which granted Merck the above-referenced tropical disease priority review voucher (the Voucher).

Reference also is made to the General Correspondence and accompanying attachments, submitted to BLA 125690 on February 4, 2020, informing the FDA of the transfer of the Voucher from Merck to BioProtection Systems Corporation, then a wholly owned subsidiary of NewLink Genetics Corporation.

In accordance with section 524(b)(2) of the Federal Food, Drug, and Cosmetic Act, please be advised that pursuant to the terms set forth in an Asset Purchase Agreement between Lumos Pharma, Inc. (“Lumos”) and Merck, dated July 27, 2020, Merck has accepted receipt and transfer of the Voucher from BioProtection Systems Corporation. Specifically, BioProtection Systems Corporation has transferred, assigned, and conveyed the Voucher back to Merck and Merck has legally accepted complete ownership of the Voucher. This sale is free and clear of all liens and provides Merck with all of BioProtection Systems Corporation and Lumos’s rights, title, and interest in, to, and under the Voucher. This letter is the receipt of transfer and acknowledgement from Merck.

Sincerely,

Merck Sharp & Dohme Corp.

By: _____

Name: _____

Title: _____

Exhibit D

Press Release

Lumos Pharma Announces Sale of Priority Review Voucher

AUSTIN, TX, July 27, 2020 (GLOBE NEWSWIRE) – Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, today announced that it has entered into a definitive agreement to sell its Priority Review Voucher (PRV) to Merck, known as MSD outside the United States and Canada.

The PRV was granted in conjunction with the approval by the U.S. Food and Drug Administration (FDA) of ERVEBO®, a vaccine developed by the Company's licensee, Merck, for the prevention of the Zaire Ebola virus disease. Under the terms of the original license agreement Lumos Pharma is entitled to retain 60% of the value of the PRV. Based upon an agreed valuation of $100 million Merck will pay Lumos $60 million. The transaction remains subject to customary closing conditions, including anti-trust review.

"We are pleased to announce the sale of the PRV, which will provide an important source of non-dilutive capital to fund additional investment in our pipeline and the evaluation of other assets for potential acquisitions or partnerships. These efforts will be critical to our growth over the coming year, and we are committed to our strategic priority of becoming leaders in the rare and ultra-rare disease space," said Rick Hawkins, Chairman, CEO and President. "Additionally, we are looking forward to initiating our Phase 2b trial of our lead candidate LUM-201 in patients with Pediatric Growth Hormone Deficiency, or PGHD, prior to the end of 2020. We believe we have the opportunity to greatly improve the standard of care for patients impacted by this disease. If approved, LUM-201 would provide an orally administered alternative to daily injections that current PGHD patients endure for many years of treatment."

Jefferies & Co. acted as exclusive financial advisor to Lumos Pharma, Inc. on this transaction.

Financial Guidance Update Related to PRV Sale

The total valuation of the PRV in the transaction was $100 million, Lumos Pharma will receive approximately $60 million which represents the Company's 60% interest in the total value of the PRV. The $60 million will be received in two noncontingent payments, $34 million in 2020 and $26 million in the first quarter of 2021. The non-dilutive funds from this transaction will provide additional capital to support the expansion of its pipeline through the in-licensing or acquisition of another novel therapeutic candidate for those suffering from rare diseases. These funds are in addition to the Company's cash position as of March 31, 2020 which was anticipated to be sufficient to support the Company's current operations through the Phase 2b clinical trial read-out.

About Lumos Pharma

Lumos Pharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of therapeutics for rare diseases. Lumos Pharma was founded and is led by a management team with longstanding experience in rare disease drug development and received early funding by leading healthcare investors, including Deerfield Management, a fund managed by Blackstone Life Sciences, Roche Venture Fund, New Enterprise Associates (NEA), Santé Ventures, and UCB. Lumos Pharma's lead therapeutic candidate is LUM-201, an oral growth hormone stimulating small molecule for the treatment of Pediatric Growth Hormone Deficiency (PGHD). If approved by the FDA, LUM-201 would provide an orally administered alternative to daily injections that current PGHD patients endure for many years of treatment. LUM-201 has received Orphan Drug Designation in both the US and EU. For more information, please visit www.lumospharma.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of Lumos Pharma, Inc. (the "Company") that involve substantial risks and uncertainties. All statements contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "forecast," "projected," "guidance," "upcoming," "will," "plan," "intend," "anticipate," "approximate," "expect," "potential," "imminent," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, the potential of an orally administered treatment regimen for PGHD and other indications, and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that the Company makes due to a number of important factors, including the effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic and other risks that could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements as discussed in "Risk Factors" and elsewhere in Lumos Pharma's definitive proxy statement, as amended and filed with the SEC on February 13, 2020, Lumos Pharma's Annual Report on Form 10-K for the year ended December 31, 2019 and other reports filed with the SEC. The forward-looking statements in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause their views to change. However, while it may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing either of the Company's views as of any date subsequent to the date of this press release.

###

Investor & Media Contact:
Lisa Miller
Lumos Pharma Investor Relations
512-648-3757 ir@lumos-pharma.com

Source: Lumos Pharma, Inc.

Schedule A
Lumos Disclosure Schedule

This Lumos Disclosure Schedule (this "***Lumos Disclosure Schedule***") is being furnished by Lumos Pharma, Inc., a Delaware corporation ("***Lumos***"), in connection with the execution of the Asset Purchase Agreement, dated as of July 27, 2020, by and among Lumos and Merck Sharp. & Dohme Corp. ("***Merck***") (the "***Agreement***"). Unless the context otherwise requires, all capitalized terms used in this Lumos Disclosure Schedule shall have the respective meanings assigned to them in the Agreement.

No reference to or disclosure of any item or other matter in this Lumos Disclosure Schedule shall be construed as an admission or indication that such item or other matter is material or that such item or other matter is required to be referred to or disclosed in this Lumos Disclosure Schedule. No reference in this Lumos Disclosure Schedule to any agreement or document shall be construed as an admission or indication that such agreement or document is enforceable or currently in effect or that there are any obligations remaining to be performed or any rights that may be exercised under such agreement or document. No disclosure in this Lumos Disclosure Schedule relating to any possible breach or violation of any agreement, law or regulation shall be construed as an admission or indication that any such breach or violation exists or has actually occurred.

Any item, information or facts set forth in any section or subsection of this Lumos Disclosure Schedule (by cross-reference or otherwise) will be deemed to disclose an exception to, limit or qualify the representations and warranties in the section and subsection of the Agreement to which they correspond and to any other representation and warranty, where the relevance to such other representation or warranty is reasonably apparent from a reading of such disclosure. This Lumos Disclosure Schedule and the information and disclosures contained in this Lumos Disclosure Schedule are intended only to qualify and limit the representations, warranties and covenants of Lumos contained in the Agreement and shall not be deemed to expand in any way the scope or effect of any of such representations, warranties or covenants.

The contents of all documents referred to in this Lumos Disclosure Schedule are incorporated by reference in this Lumos Disclosure Schedule as though fully set forth in this Lumos Disclosure Schedule. The bold- faced headings contained in this Lumos Disclosure Schedule are included for convenience only, and are not intended to limit the effect of the disclosures contained in this Lumos Disclosure Schedule or to expand the scope of the information required to be disclosed in this Lumos Disclosure Schedule.

ARTICLE 4
REPRESENTATIONS AND WARRANTIES OF LUMOS

Lumos has received correspondence from Yale University relating to the research and construction of the Ebola vaccine product by Lumos's licensor, PHAC, who, along with Lumos is party to the PHAC Agreement.

Exhibit 10.2

AMENDMENT NO. 1 TO LICENSE AGREEMENT

This AMENDMENT NO. 1 TO LICENSE AGREEMENT made as of August 12, 2020 (the "**Amendment Date**") is made by and between MERCK SHARP & DOHME CORP., a New Jersey corporation ("**Merck**") and Lumos Pharma, Inc. ("**Lumos**"), a Delaware corporation (this "**Amendment**"), pursuant to that certain License Agreement dated October 22, 2013, by and between Merck and Ammonett Pharma LLC, a limited liability company incorporated under the laws of Delaware (as may be further amended, restated, supplemented or otherwise modified after the date hereof, the "**Agreement**"). Capitalized terms used but not otherwise defined herein shall have the meaning ascribed to such terms by the Agreement. Lumos and Merck are each referred to herein as a "**Party**" and collectively, the "**Parties**".

WHEREAS, Ammonett and Lumos entered into that certain Asset Purchase Agreement as of July 26, 2018, pursuant to which Lumos purchased from Ammonett, Ammonett's right, title and interest in the Agreement and Lumos assumed from Ammonett, Ammonett's obligations thereunder;

WHEREAS, Section 14.06 of the Agreement provides that the Agreement may not be altered, amended, changed, waived or added to except as reduced to writing and signed by an authorized officer of each Party;

WHEREAS, the Parties desire to make certain changes to the Agreement to clarify the Parties' rights and obligations therein;

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Amendment, the Parties agree as follows:

a. **Certain Amendments.**

i. Article I of the Agreement (Definitions) is hereby revised by including the following definition in the alphabetically appropriate location:

> "**Diagnostic Purposes**" shall mean the use of Licensed Compound or Licensed Product for the diagnosis of any disease, disorder or condition in humans, including, but not limited to, use as a companion diagnostic or predictive enrichment marker, excluding any diagnosis of Autism Spectrum Disorders as defined in the Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders.

ii. Section 2.01(a) of the Agreement (License Grant – Development License) is hereby deleted in its entirety and replaced with the following:

"(a) **Development License**.

a. **Exclusive 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(a)(ii) and 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. **Non-Exclusive License**. A royalty bearing license in the Territory for Diagnostic Purposes, with the right to grant sublicenses as provided herein, under the Compound Patent Rights, which Compound Patent Rights license shall be non-exclusive to Develop, Manufacture, have Manufactured, use, import, export and Commercialize Licensed Compound and Licensed Product for Diagnostic Purposes in the Territory during the Term."

iii. Section 2.01(b) of the Agreement (License Grant – Know-How License) is hereby deleted in its entirety and replaced with the following:

"(b) **Know-How License**.

a. **Exclusive 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.

b. **Non-Exclusive License**. A royalty bearing non-exclusive license in the Territory for Diagnostic Purposes, 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 for Diagnostic Purposes in the Territory during the Term."

iv. Section 2.01(c) of the Agreement (License Grant – Research License) is hereby deleted in its entirety and replaced with the following:

"(c) **Research License**. A license, co-exclusive with Merck and its Affiliates, with the 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 and for Diagnostic Purposes 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."

v. Section 2.02 (Non-Exclusive License Grant) is hereby deleted in its entirety and replaced with the following:

"**Non-Exclusive License Grant**. Merck hereby grants to Licensee a non-exclusive license in the Territory in the Field and for Diagnostic Purposes 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 and for Diagnostic Purposes in the Territory during the Term in accordance with the Development Plan."

vi. Section 2.05(d) (Sublicense Agreements) is hereby deleted in its entirety and replaced with the following:

"(d) may permit the sublicensee to grant further sublicenses and/or the right to enforce the Compound Patent Rights subject to Merck's prior written consent for such further sublicense or right to enforce, such consent not to be unreasonably withheld;"

vii. Section 3.05 (Contract Sales Force) is hereby deleted in its entirety and replaced with the following:

"**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; provided, that, in the event that Licensee enters into a Development or Commercial Arrangement with a Third Party during the Option Deferral Period, then such Third Party may hire a Contract Sales Force without the prior written consent of Merck."

viii. Section 3.06 is hereby amended by adding a new section (c) containing the following:

"(c) In the event that either (i) Merck does not submit terms for a Development or Commercial Arrangement within 45 days after the delivery of the Option Notice or (ii) the Parties, despite negotiating in good faith for a period of sixty (60) days pursuant to Section 3.06(b) (or any mutually agreed upon extension), are unable to enter into a definitive agreement for such Development or Commercial Arrangement (each of (i) and (ii), an "Option Deferral Event"), then until the first anniversary of the date of such Option Deferral Event (the "Option Deferral Period"), Licensee may enter into a Development or Commercial Arrangement with any Third Party with respect to such Licensed Product in the Field without submitting a new Option Notice to Merck for each new Third Party relationship."

b. **Notices**.

i. Section 14.07 (Notices) is hereby revised by deleting the address following "if to Licensee, to:" and replacing such addresses with the following:

if to Licensee, to:

Attn: General Counsel
Lumos Pharma, Inc.
4200 Marathon Blvd., Suite 200
Austin, TX 78756

with a copy to, which shall not constitute notice:

Attn: Legal Department
Lumos Pharma, Inc.
2503 S. Loop Dr., Suite 5100
Ames, IA 50010

ii. Section 14.07 (Notices) is hereby revised by deleting the address following "if to Merck, to:" and replacing such addresses with the following:

if to Merck, to:

Merck Sharp & Dohme Corp.
2000 Galloping Hill Road
PO Box 539
Mailstop K-1-4161
Kenilworth, NJ 07033-1310
Attention: Senior Vice President, Business Development

and

Merck Sharp & Dohme Corp.
One Merck Drive, NK – 08889-0100
Whitehouse Station,
Attention: Office of Secretary
Email: Office.secretary@merck.com

c. **Miscellaneous**.

i. Effect of Amendment. This Amendment shall modify and amend the Agreement to the extent, and only to the extent, expressly set forth herein (it being the intent of the Parties that all of the terms and provisions of the Agreement that are not expressly amended, modified, waived or replaced hereunder shall be unaltered and shall remain in full force and effect and that the execution, delivery and performance of this Amendment shall not operate as a waiver of or consent to any past, present or future breach of any provision of the Agreement). From and after

the Amendment Date, all references in the Agreement to “this Agreement,” “herein,” “hereunder,” and words of like import shall mean and refer to the Agreement as amended hereby.

ii. Captions. Section 14.12 of the Agreement is hereby incorporated by reference *mutatis mutandis*.

iii. Counterparts. Section 14.11 of the Agreement is hereby incorporated by reference *mutatis mutandis*.

iv. Severability. Section 14.09 of the Agreement is hereby incorporated by reference *mutatis mutandis*.

v. Independent Relationship. Section 14.04 of the Agreement is hereby incorporated by reference *mutatis mutandis*.

vi. Governing Law; Dispute Resolution. Section 14.02 (Governing Law) and Article XIII (Dispute Resolution) of the Agreement are hereby incorporated by reference *mutatis mutandis*.

vii. Amendment; Waiver. Section 14.06 and Section 14.03 of the Agreement is hereby incorporated by reference *mutatis mutandis*.

viii. No Third Party Beneficiaries. This Amendment shall not confer any rights or remedies upon any Person other than the Parties and their respective successors and permitted assigns.

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Amendment Date.

MERCK SHARP & DOHME CORP. **LUMOS PHARMA, INC.**

By: /s/Juanita Lee By: /s/Richard Hawkins
Name: Juanita Lee Name: Richard J. Hawkins
Title: Assistant Treasurer Title: President and CEO

EXHIBIT 31.1

CERTIFICATION

I, Richard J. Hawkins, certify that:

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

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

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

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

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

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles

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

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

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

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

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

Date: August 14, 2020

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

EXHIBIT 31.2

CERTIFICATION

I, Carl W. Langren, certify that:

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

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

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

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

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

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: August 14, 2020

By: /s/ Carl W. Langren
Carl W. Langren
Chief Financial Officer and Secretary
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION

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

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2020, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

In Witness Whereof, the undersigned have set their hands hereto as of August 14, 2020.

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

By: /s/ Carl W. Langren
Carl W. Langren
Chief Financial Officer and Secretary
(Principal Financial Officer)

"This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."