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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, 2024.

☐ **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 July 26, 2024, there were 8,124,037 shares of the registrant’s Common Stock, par value $0.01 per share, outstanding.

Lumos Pharma, Inc.

FORM 10-Q

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Forward-Looking Statements

This quarterly report on Form 10-Q for the quarter ended June 30, 2024 (this "Quarterly Report") contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements involve risks and uncertainties and reflect our current views with respect to, among other things, future events and our financial performance. When used in this report, the words "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "expect," "indicate," "seek," "should," "would," and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. These forward-looking statements are not historical facts, and are based on current expectations, estimates and projections about our industry, management's beliefs and certain assumptions made by management, many of which, by their nature, are inherently uncertain and beyond our control. Accordingly, we caution you that any such forward-looking statements are not guarantees of future performance and are subject to risks, assumptions, estimates and uncertainties that are difficult to predict. Although we believe that the expectations reflected in these forward-looking statements are reasonable as of the date of this Quarterly Report, actual results may prove to be materially different from the results expressed or implied by the forward-looking statements.

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

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

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

PART I - FINANCIAL INFORMATION
Item 1. Condensed Consolidated Financial Statements

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

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 16,799	$ 35,078
Short-term investments	—	999
Prepaid expenses and other current assets	3,925	3,748
Other receivables	168	210
Total current assets	20,892	40,035
Non-current assets:		
Right-of-use asset	463	603
Total assets	$ 21,355	$ 40,638
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 337	$ 890
Accrued expenses	4,294	5,858
Current portion of lease liability	304	282
Total current liabilities	4,935	7,030
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	145	303
Total liabilities	11,080	13,333
Commitments and contingencies		
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value: Authorized shares -5,000,000 at June 30, 2024 and December 31, 2023; issued and outstanding shares - 0 at June 30, 2024 and December 31, 2023	—	—
Common stock, $0.01 par value: Authorized shares -75,000,000 at June 30, 2024 and December 31, 2023; issued shares - 8,151,900 and 8,125,728 at June 30, 2024 and December 31, 2023, respectively, and outstanding shares - 8,123,186 and 8,102,555 at June 30, 2024 and December 31, 2023, respectively	81	81
Treasury stock, at cost, 28,714 and 23,173 shares at June 30, 2024 and December 31, 2023, respectively	(212)	(196)
Additional paid-in capital	189,915	188,937
Accumulated deficit	(179,509)	(161,517)
Total stockholders' equity	10,275	27,305
Total liabilities and stockholders' equity	$ 21,355	$ 40,638

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
Royalty revenue	$ 488	$ 527	$ 653	$ 1,218
Total revenues	488	527	653	1,218
Operating expenses:				
Research and development	4,629	6,024	11,877	10,393
General and administrative	3,682	4,146	7,461	8,503
Total operating expenses	8,311	10,170	19,338	18,896
Loss from operations	(7,823)	(9,643)	(18,685)	(17,678)
Other income and expense:				
Other income, net	202	124	465	243
Interest income	70	559	228	1,129
Other income, net	272	683	693	1,372
Net loss before taxes	$ (7,551)	$ (8,960)	$ (17,992)	$ (16,306)
Income tax benefit	—	29	—	29
Net loss	$ (7,551)	$ (8,931)	$ (17,992)	$ (16,277)
Net loss per share:				
Basic and diluted	$ (0.93)	$ (1.09)	$ (2.22)	$ (1.98)
Weighted average number of common shares outstanding:				
Basic and diluted	8,112,566	8,164,603	8,107,528	8,205,625
Other comprehensive loss:				
Unrealized loss on short-term investments	—	(6)	—	(2)
Total comprehensive loss	$ (7,551)	$ (8,937)	$ (17,992)	$ (16,279)

See accompanying notes to condensed consolidated financial statements.

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

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	8,267,968	$ 82	15,740	$ (170)	$ 187,164	$ (127,483)	$ (9)	$ 59,584
Stock-based compensation	—	—	—	—	586	—	—	586
Stock issued upon vesting of restricted stock units	4,029	—	—	—	—	—	—	—
Shares surrendered for tax withholding on vested awards	(1,007)	—	1,007	(4)	—	—	—	(4)
Repurchases of common stock	(87,694)	(1)	—	—	(304)	—	—	(305)
Other comprehensive income	—	—	—	—	—	—	4	4
Net loss	—	—	—	—	—	(7,346)	—	(7,346)
Balance at March 31, 2023	8,183,296	81	16,747	(174)	187,446	(134,829)	(5)	52,519
Stock-based compensation	—	—	—	—	653	—	—	653
Sale of shares under stock purchase plan	6,425	—	—	—	18	—	—	18
Stock issued upon vesting of restricted stock units	15,372	—	—	—	—	—	—	—
Shares surrendered for tax withholding on vested awards	(3,828)	—	3,828	(13)	—	—	—	(13)
Repurchase of common stock	(159,920)	(1)	—	—	(578)	—	—	(579)
Other comprehensive loss	—	—	—	—	—	—	(6)	(6)
Net loss	—	—	—	—	—	(8,931)	—	(8,931)
Balance at June 30, 2023	8,041,345	$ 80	20,575	$ (187)	$ 187,539	$ (143,760)	$ (11)	$ 43,661
Balance at December 31, 2023	8,102,555	$ 81	23,173	$ (196)	$ 188,937	$ (161,517)	$ —	$ 27,305
Stock-based compensation	—	—	—	—	580	—	—	580
Stock issued upon vesting of restricted stock units	6,279	—	—	—	—	—	—	—
Shares surrendered for tax withholding on vested awards	(1,713)	—	1,713	(5)	—	—	—	(5)
Net loss	—	—	—	—	—	(10,441)	—	(10,441)
Balance at March 31, 2024	8,107,121	81	24,886	(201)	189,517	(171,958)	—	17,439
Stock-based compensation	—	—	—	—	387	—	—	387
Stock issued upon vesting of restricted stock units	14,188	—	—	—	—	—	—	—
Shares surrendered for tax withholding on vested awards	(3,828)	—	3,828	(11)	—	—	—	(11)
Stock issued under stock purchase plan	5,705	—	—	—	11	—	—	11
Net loss	—	—	—	—	—	(7,551)	—	(7,551)
Balance at June 30, 2024	8,123,186	$ 81	28,714	$ (212)	$ 189,915	$ (179,509)	$ —	$ 10,275

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2024	**2023**
Cash Flows From Operating Activities		
Net loss	$ (17,992)	$ (16,277)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	967	1,239
Depreciation and amortization	4	18
Other income, net	(1)	(271)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(177)	(474)
Other receivables	42	(10)
Accounts payable and accrued expenses	(2,117)	(107)
Net cash used in operating activities	(19,274)	(15,882)
Cash Flows From Investing Activities		
Purchases of marketable securities	—	(6,380)
Maturities of marketable securities	1,000	5,000
Net cash provided by (used in) investing activities	1,000	(1,380)
Cash Flows From Financing Activities		
Sale of shares under stock purchase plan	11	18
Payment for tax withholding on vested awards	(16)	(17)
Repurchases of common stock	—	(884)
Net cash used in financing activities	(5)	(883)
Net decrease in cash and cash equivalents	(18,279)	(18,145)
Cash and cash equivalents at beginning of period	35,078	56,007
Cash and cash equivalents at end of period	$ 16,799	$ 37,862

See accompanying notes to condensed consolidated financial statements.

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

1. Description of Business

Organization and Nature of Operations

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

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

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

Liquidity and Going Concern

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

As of June 30, 2024, the Company had approximately $16.8 million of cash and cash equivalents. The Company's accumulated deficit at June 30, 2024 was approximately $179.5 million. Given its current development plans and cash management efforts, the Company anticipates its cash resources will be sufficient to fund operations into the first quarter of 2025.

However, based on the Company's current cash forecast and the Company's dependence on its ability to obtain additional financing to fund its operations in advancing the PGHD program into a Phase 3 trial, the Company concluded that its available cash and cash equivalents as of June 30, 2024 may not be sufficient to fund its operations for at least 12 months from the filing date of this Quarterly Report, and thus substantial doubt exists as to the Company's ability to continue as a going concern.

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

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

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Lumos and its wholly-owned subsidiaries and have been prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP"). All significant intercompany accounts and transactions are eliminated in consolidation.

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. GAAP for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments of a normal and recurring nature considered necessary for a fair presentation have been included in the accompanying condensed consolidated financial statements. The results of operations for the interim period are not necessarily indicative of the results that will be realized for the entire fiscal year. These condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements and accompanying notes thereto included in the Company's 2023 Annual Report filed on Form 10-K with the SEC on March 7, 2024.

Use of Estimates

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

As of June 30, 2024, the Company's significant accounting policies are consistent with those discussed in Note 2 - "Summary of Significant Accounting Policies and Recent Accounting Pronouncements" of its consolidated financial statements included in the Company's 2023 Annual Report filed on Form 10-K with the SEC on March 7, 2024.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures* . This ASU requires interim and annual disclosure of significant segment expenses that are regularly provided to the chief operating decision-maker ("CODM") and included within the reported measure of a segment's profit or loss, requires interim disclosures about a reportable segment's profit or loss and assets that are currently required annually, requires disclosure of the position and title of the CODM, clarifies circumstances in which an entity can disclose multiple segment measures of profit or loss, and contains other disclosure requirements. This authoritative guidance is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the effect of this new guidance on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740)—Improvements to Income Tax Disclosures* . This ASU requires that reporting entities disclose specific categories in the effective tax rate reconciliation as well as information about income taxes paid. The authoritative guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the effect of this new guidance on its consolidated financial statements.

3. License and Asset Purchase Agreements

License and LUM-201 Asset Purchase Agreements

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

The Lumos Merck Agreement, which grants Lumos (as successor in interest to Ammonett) worldwide, exclusive, sublicensable (subject to Merck's consent in the United States, major European countries and Japan, such consent not to be unreasonably withheld) rights under specified patents and know-how to develop, manufacture and commercialize LUM-201 for any and all indications, excluding Autism Spectrum Disorders as defined in the Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders.

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

Under the APA, the Company paid Ammonett an upfront fee of $ 3.5 million which was recorded as research and development expense in 2018. The Company may also incur development milestone payments totaling up to $17.0 million for achievement of specified milestones on the first indication that Lumos pursues, of which $2.0 million was paid in March 2024, and up to $ 14.0 million for achievements of specified milestones on the second indication that Lumos pursues, sales milestone payments totaling up to $55.0 million on worldwide product sales, and royalty payments based on worldwide product sales, as discussed below.

Under the Lumos Merck Agreement, Lumos will be required to pay Merck substantial development milestone payments for achievement of specified milestones relating to each of the first and second indications. Total potential development milestone payments are required of up to $14 million for the first indication that Lumos pursues and up to $8.5 million for the second indication that Lumos pursues. Tiered sales milestone payments totaling up to $80.0 million are required on worldwide net product sales up to $ 1.0 billion, and royalty payments based on product sales are required if product sales are achieved.

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

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

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

License and PRV Asset Purchase Agreements

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

announced that the FDA approved its application for ERVEBO® (Ebola Zaire Vaccine, Live) for the prevention of disease caused by Zaire Ebola virus in individuals 18 years of age and older and grant of the PRV.

Under the NewLink Merck Agreement, as amended, the Company has earned and has the potential to continue to earn royalties on sales of the vaccine in certain countries. However, we believe that the market for the vaccine will be limited primarily to areas in the developing world that are excluded from royalty payment or where the vaccine is donated or sold at low or no margin, and therefore we do not expect to receive material royalty payments from Merck in the foreseeable future. For each of the three months ended June 30, 2024 and 2023, the Company recognized revenues of $0.5 million, and recognized revenues of $ 0.7 million and $1.2 million, respectively, for the six months ended June 30, 2024 and 2023, for royalties related to royalty-bearing commercial sales of the vaccine.

Additionally, per the terms of the licensing agreement with the PHAC, the Company has an obligation to pay a royalty fee to the PHAC for any royalty amounts earned. For each of the three months ended June 30, 2024 and 2023, the Company incurred royalty expense of $0.3 million, and incurred royalty expense of $0.4 million and $0.8 million, respectively, for the six months ended June 30, 2024 and 2023, for royalties related to royalty-bearing commercial sales of the vaccine. Royalty expenses are included within general and administrative expenses in the consolidated statements of operations.

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

4. Financial Instruments

Fair Value

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

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

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

	As of June 30, 2024		
	Level 1	**Level 2**	**Total**
Cash equivalents:			
Money market funds	$ 15,857	$ —	$ 15,857
Total cash equivalents	$ 15,857	$ —	$ 15,857

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

As of June 30, 2024 and December 31, 2023, the Company had no Level 3 assets or liabilities.

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

Contractual Maturities of Investments

As of June 30, 2024, all of the Company's available-for-sale investments were due within one year or less.

Available-for-sale Investments

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

	As of June 30, 2024		
	Amortized Cost	Unrealized Losses	Fair Value
Cash equivalents:			
Money market funds	$ 15,857	$ —	$ 15,857
Total cash equivalents	$ 15,857	$ —	$ 15,857

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

As of June 30, 2024 and December 31, 2023, there were no material unrealized gains associated with the Company's available-for-sale investments.

5. Accrued Expenses

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

	June 30, 2024	December 31, 2023
Compensation and related benefits	$ 2,507	$ 3,472
Clinical and contract manufacturing expenses	1,181	1,790
Other	606	596
Total accrued expenses	$ 4,294	$ 5,858

6. Stock-Based Compensation and Employee Benefit Plans

Stock Options and Performance Stock Options

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

In connection with the Merger, the Company assumed NewLink's 2009 Equity Incentive Plan which was effective since July 2009 and was subsequently amended on May 9, 2019 (the "2019 Plan"). The 2019 Plan has a 10 year term from the Board adoption date of March 22, 2019 and on January 1 of each year through January 1, 2029, in accordance with an "evergreen provision", a number of shares of common stock in an amount equal to 3% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year or such lesser amount of shares (or no shares) approved by the Board, will be added to the shares reserved under the 2019 Plan. The 2019 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards and stock appreciation rights to officers, employees, members of the Board, advisors, and consultants to the Company. As of June 30, 2024, we had 688,134 shares available for grant under the 2019 Plan.

2010 Non-Employee Directors' Stock Award Plan

In connection with the Merger, the Company assumed NewLink's 2010 Non-Employee Directors' Stock Award Plan (the Directors' Plan) which was effective on November 10, 2011. As of June 30, 2024, 5,624 shares remain available for grant under the Directors' Plan.

2010 Employee Stock Purchase Plan

In connection with the Merger, the Company assumed NewLink's 2010 Employee Stock Purchase Plan, as amended (the "2010 Purchase Plan"), which was effective on November 10, 2011. As of June 30, 2024, 30,241 shares remain available for issuance under the 2010 Purchase Plan. On July 22, 2021, the Board approved an amendment and restatement of the 2010 Purchase Plan (the "A&R ESPP"), and established a special offering period under the A&R ESPP beginning September 1, 2021 and lasting until June 30, 2023, subject to restart provisions as described within the A&R ESPP. The special offering period under the A&R ESPP was fully contingent upon stockholder approval of the A&R ESPP at the 2022 Annual Meeting of Stockholders. The A&R ESPP provided for an increase in the number of shares reserved for issuance under the A&R ESPP by 60,000 shares. On May 4, 2022, at the 2022 Annual Meeting of Stockholders, the A&R ESPP was approved. On June 30, 2022, December 30, 2022, June 30, 2023, and June 30, 2024, the restart provision was triggered, resulting in new offering periods. The current offering period is from July 1, 2024 through June 30, 2026.

Share-Based Compensation Expense

Stock-based compensation expenses included in the Company's condensed consolidated statements of operations for the three and six months ended June 30, 2024 and 2023 were (in thousands):

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 102	$ 192	$ 244	$ 349
General and administrative	285	461	723	890
Total	$ 387	$ 653	$ 967	$ 1,239

As of June 30, 2024, we had unrecognized compensation cost of $ 2.3 million and the weighted-average period over which it is expected to be recognized is 2.2 years.

7. Long-Term Debt and Conversion to Royalty Obligation

In March 2005, NewLink entered into a $6.0 million forgivable loan agreement with the Iowa Department of Economic Development (the "IDED"). Under the agreement, in the absence of default, there were no principal or interest payments due until the completion date for the project. This loan was converted into a royalty obligation under the terms of a settlement agreement entered into on March 26, 2012 (the "IEDA Agreement"), with the Iowa Economic Development Authority (the "IEDA"), as successor in interest to the IDED. As no payments are expected in the next 12 months, the entire royalty obligation of $6.0 million, which we assumed in connection with the Merger, is classified as a long-term liability as of June 30, 2024.

8. Income Taxes

For the three months ended June 30, 2024 and 2023, the Company recorded an income tax benefit of $ 0 and $29,000, respectively. For the six months ended June 30, 2024 and 2023, the Company recorded an income tax benefit of $0 and $29,000, respectively. The income tax amount for each of the three and six months ended June 30, 2024 and 2023 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to an increase in the 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. Due to the uncertainty of the Company's ability to realize the benefit of the deferred tax assets, the net deferred tax assets are fully offset by a valuation allowance at June 30, 2024.

Based on Section 382 ownership change analyses through March 18, 2020, as a result of the Merger, both historical NewLink and Private Lumos experienced Section 382 ownership changes on March 18, 2020. These ownership changes limit our ability to utilize federal net operating loss carryforwards and certain other tax attributes that accrued prior to the respective ownership changes of us and our subsidiaries and may continue to limit our ability to utilize such attributes in the future. Based on subsequent analyses, we did not experience a Section 382 ownership change from March 19, 2020 through December 31, 2022.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net loss	$ (7,551)	$ (8,931)	$ (17,992)	$ (16,277)
Weighted-average shares outstanding – Basic and diluted	8,112,566	8,164,603	8,107,528	8,205,625
Net loss per share – Basic and diluted	$ (0.93)	$ (1.09)	$ (2.22)	$ (1.98)
Anti-dilutive stock options	1,640,843	1,488,088	1,640,843	1,488,088
Anti-dilutive restricted stock units	57,113	53,868	57,113	53,868
Total anti-dilutive common stock equivalents excluded	1,697,956	1,541,956	1,697,956	1,541,956

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

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included in Part I, Item 1 of this quarterly report on Form 10-Q for the quarter ended June 30, 2024 (this "Quarterly Report"). This Quarterly Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, such statements are subject to the "safe harbor" created by those sections and involve risks and uncertainties. Forward-looking statements are based on our management's beliefs and assumptions and on information available to our management as of the date hereof. As a result of many factors, such as those set forth unde r "Item 1A. Risk Factors" included in our 2023 Annual Report and Part II, "Item 1A. Risk Factors" in this Quarterly Report, our actual results may differ materially from those anticipated in these forward-looking statements, accordingly, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Overview

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

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

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

Strategic Update

We have engaged Piper Sandler as our financial advisor to help evaluate strategic opportunities to maximize stockholder value and advance the LUM-201 platform.

LUM-201 Growth Hormone Secretagogue

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

If approved, LUM-201 has the potential to become the first approved oral GH secretagogue to treat rare endocrine disorders associated with GH deficiencies, starting with PGHD, providing an alternative to the current standard regimen of recombinant growth hormone product injections. A secretagogue is a substance that stimulates the secretion or release of another substance. LUM-201 stimulates the release of GH and is referred to as a GH secretagogue.

LUM-201 stimulates GH via the GH secretagogue receptor (GHSR1a), also known as the ghrelin receptor, and also suppresses the release of somatostatin, thus providing a differentiated mechanism of action to treat some rare endocrine disorders (involving a deficiency of GH) by increasing the amplitude of endogenous, pulsatile GH secretion. LUM-201's stimulatory effect is regulated by both circulating levels of GH and its down-stream mediator insulin-like growth factor ("IGF-1") which at supraphysiological levels feedbacks or negatively regulates additional release of GH from the pituitary, hence protecting against hyperstimulation of the pituitary.

Overview of PGHD

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

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

The main therapeutic goal in PGHD is to restore growth and improve body composition, enabling short children to achieve normal height and prevent complications that could involve metabolic abnormalities, cognitive deficits and reduced quality of life. The current standard of care for PGHD is limited to daily subcutaneous injections of rhGH with a treatment cycle lasting up to an average of seven years. Poor compliance with daily rhGH injections during treatment can result in an adverse impact on growth and body composition. Over the past three years, the FDA has approved three new once-weekly growth hormone injection products. Based on our market research, we believe that many providers and patients will have a preference for an orally administered treatment, when available.

Clinical Trial Results and Development Plans

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

The primary endpoint of the study is preliminary validation of our predictive enrichment marker (“PEM”) patient selection strategy as evidenced by the percentage of selected patients who grow in response to LUM-201. Each patient enrolled in our Phase 2 clinical trials is given a single dose of LUM-201 at the 0.8 mg/kg/day dose to determine if they meet the cut-off criteria for enrollment, which is a baseline IGF-1 > 30 ng/ml and stimulated GH ≥5 ng/ml. The primary efficacy endpoint is annualized height velocity (“AHV”). Secondary endpoints include selection of a pediatric dose of LUM-201 for future studies including Phase 3 and determination of the degree of repeatability of the PEM selection process in PEM positive patients screened for participation in OraGrowthH210.

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

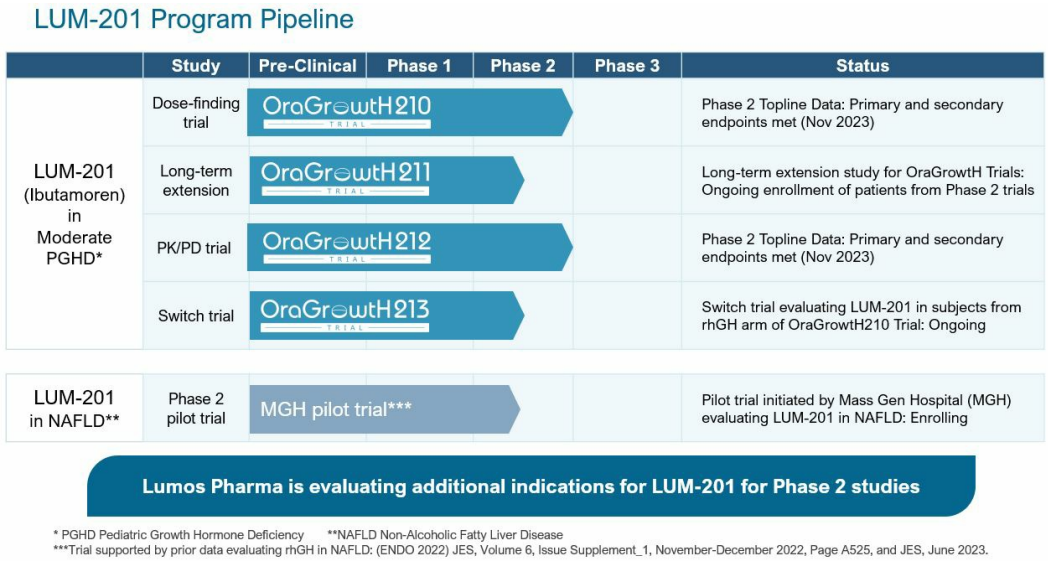
During the first quarter of 2022, we initiated our OraGrowthH213 Trial (the “OraGrowthH213 Trial,” and together with the OraGrowthH210 Trial, the OraGrowthH211 Trial, and the OraGrowthH212 Trial, the “OraGrowthH Trials”), an open-label, multi-center, Phase 2 study evaluating the growth effects and safety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

We announced in November 2023 that our OraGrowthH210 and OraGrowthH212 Trials met all primary and secondary endpoints. Our OraGrowthH210 data demonstrated that the 1.6 mg/kg/day LUM-201 dose produced a mean AHV of 8.2 cm/yr at six months on treatment for moderate PGHD subjects, in line with historical data in moderate PGHD patients. Additionally, at twelve months on treatment, a durable effect was also observed with LUM-201 achieving AHV of 8.0 cm/yr at the 1.6 mg/kg dose, within the targeted 2 cm/yr margin of the comparator injectable rhGH arm. Data also provided preliminary validation of

the PEM strategy, with prespecified primary and secondary outcomes met, de-risking our patient selection for our Phase 3 program. Data from the OraGrowthH212 Trial confirmed that LUM-201's unique pulsatile mechanism produces an increase in the growth rates while restoring growth hormone secretion and IGF-1 to within normal ranges. LUM-201 continues to have a favorable safety profile with no significant adverse events identified in either of our Phase 2 trials conducted thus far. On May 14, 2024, we announced updated 12-month and 24-month data from our OraGrowthH Trials which continue to show durable effect and significant improvement over baseline AHV.

We announced in May 2024, that we had held a collaborative end-of-phase 2 meeting with the FDA, where we reviewed the promising data from our OraGrowthH210 and OraGrowthH212 Trials. During our meeting, the FDA acknowledged that LUM-201 is not a growth hormone nor a growth hormone mimetic, and agreed that it is instead a novel growth hormone secretagogue. Relatedly, the FDA indicated that a placebo-controlled Phase 3 trial design can be an appropriate option for our Phase 3 trial. In such placebo-controlled trial, it would not include an active comparator arm with a non-inferiority margin. Rather, it would need to demonstrate clinically meaningful improvement in growth compared to placebo. Further, the FDA noted that a 12-month duration is more appropriate for such a placebo-controlled trial, as a 6-month trial has not been previously accepted as a pivotal trial used to demonstrate improvement in height. Based on the FDA feedback and along with the updated trial data, we plan to move forward with our design of a single Phase 3 clinical trial, which we believe has the potential to be registrational, that will be a double-blinded, placebo-controlled clinical trial with a 2:1 randomization in approximately 150 patients. Advanced planning for this trial is underway, and we expect to finalize design details after we have a Type C meeting with the FDA in the third quarter of 2024. Following the Type C meeting, we expect to be in a position to initiate a Phase 3 trial in the second quarter of 2025, subject to FDA approval and completion of a financing transaction to fund the trial.

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



Potential expansion of LUM-201 into additional indications

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

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

We continue to explore various development paths to expand into additional indications for LUM-201 and we are actively reviewing the mechanism of action of LUM-201 in a subset of affected patients in other potential indications. Based on our initial review to date, we have narrowed our focus for the next indications to include Idiopathic Short Stature, with a focus on the Asia markets, Prader Willi Syndrome, and cardiometabolic indications, where we see attractive global opportunities. We have prioritized our resources for PGHD and currently plan to advance planning for Prader Willi Syndrome, Idiopathic Short Stature, and cardiometabolic indications as our financial resources allow.

Orphan Drug Designation

LUM-201 received ODD in the United States and the European Union for GHD in 2017. The United States patent “Detecting and Treating Growth Hormone Deficiency” has been issued with an expiration in 2036. Related patents have been issued in the European Union, Australia, Canada, Israel, Japan, South Korea, Hong Kong, Singapore, and Ukraine, with related patent applications pending in multiple other jurisdictions.

Intellectual Property

Lumos acquired LUM-201 from Ammonett Pharma LLC (“Ammonett”) in July 2018. LUM-201 received an Orphan Drug Designation (“ODD”) in the United States and the European Union for Growth Hormone Deficiency (“GHD”) in 2017. The United States patent “Detecting and Treating Growth Hormone Deficiency” has been issued with an expiration in 2036. Related patents have been issued in the European Union, Australia, Canada, Israel, Japan, South Korea, Hong Kong, Singapore, and Ukraine, with related patent applications pending in multiple other jurisdictions. In March 2024, we were granted a patent titled “Compactable Oral Formulations of Ibutamoren,” which contains claims directed to certain improved LUM-201 drug product formulations we intend to utilize in our LUM-201 Phase 3 trial and ultimately commercialize. The novel formulation takes advantage of unique properties of LUM-201, namely the ability to compress a desired quantity of drug product into a tablet smaller than typical tablets. We believe the compressed tablet will enable a commercial product offering well suited for the full range of potential patient preferences and will result in a reduced treatment burden for the patient population. The grant of this novel formulation patent provides protection through November 2042 for the commercialized version of LUM-201.

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

Ebola Vaccine

In November 2014, NewLink entered into the NewLink Merck Agreement with Merck to develop and potentially commercialize its Ebola vaccine rVSVΔG-ZEBOV that it licensed from PHAC. rVSVΔG-ZEBOV was also eligible to receive a PRV if approval was granted by the FDA, with the Company entitled to 60% of the PRV value obtained through sale, transfer or other disposition of the PRV. On December 20, 2019, Merck announced that the FDA approved its application for ERVEBO® (Ebola Zaire Vaccine, Live) for the prevention of disease caused by Zaire Ebola virus in individuals 18 years of age and older. Pursuant to the asset purchase agreement, Merck agreed, among other things, to pay us for the PRV in two installments. As required by the agreement, Merck paid us $34.0 million on September 1, 2020 and $26.0 million on January 11, 2021.

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

Oncology Candidates

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

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

Financial Overview

Revenue

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

Research and Development Expenses

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

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

General and Administrative Expenses

General and administrative expenses consist primarily of professional fees for legal, auditing, tax and business consulting services, personnel expenses and travel costs. We expect that general and administrative expenses will increase in the future as we expand our operating activities.

Critical Accounting Policies and Significant Judgments and Estimates

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

There have been no material changes to the critical accounting policies, or the underlying estimates and assumptions, from those discussed in Item 7, “Management's Discussion and Analysis of Financial Condition and Results of Operations” of our 2023 Annual Report.

Results of Operations

Comparison of the Three Months Ended June 30, 2024 and 2023:

	Three Months Ended June 30,			
	2024	2023	Change in $	Change in %
	(in thousands)		(in thousands)	
Revenues:				
Royalty revenue	$ 488	$ 527	(39)	(7) %
Total revenues	488	527		
Operating expenses:				
Research and development	4,629	6,024	(1,395)	(23) %
General and administrative	3,682	4,146	(464)	(11) %
Total operating expenses	8,311	10,170		
Other income, net	272	683	(411)	(60) %
Income tax benefit	—	29	(29)	(100) %
Net loss	$ (7,551)	$ (8,931)		

Revenues. Revenues decreased by $39,000 for the three months ended June 30, 2024 compared to the same period in 2023 due to a reduction in royalties earned related to sales of ERVEBO®.

Research and Development Expenses. Research and development expenses decreased by $1.4 million for the three months ended June 30, 2024 compared to the same period in 2023 primarily due to decreases of $1.1 million in contract manufacturing expenses, $0.3 million in personnel-related expenses and $0.2 million in clinical trial expenses, offset by an increase of $0.2 million in consulting expenses.

General and Administrative Expenses. General and administrative expenses decreased by $0.5 million for the three months ended June 30, 2024 compared to the same period in 2023 primarily due to decreases of $0.2 million in personnel-related expenses, $0.1 million in travel expenses, $0.1 million in consulting expenses and $0.1 million in other expenses.

Other Income, net. Other income, net decreased by $0.4 million for the three months ended June 30, 2024 compared to the same period in 2023 primarily due to a decrease in interest income driven by a decrease in short-term investments.

Comparison of the Six Months Ended June 30, 2024 and 2023

	Six Months Ended June 30,			
	2024	2023	Change in $	Change in %
	(in thousands)		(in thousands)	
Revenues:				
Royalty revenue	$ 653	$ 1,218	(565)	(46) %
Total revenues	653	1,218		
Operating expenses:				
Research and development	11,877	10,393	1,484	14 %
General and administrative	7,461	8,503	(1,042)	(12) %
Total operating expenses	19,338	18,896		
Other income, net	693	1,372	(679)	(49) %
Income tax benefit	—	29	(29)	(100) %
Net loss	$ (17,992)	$ (16,277)		

Revenues. Revenues decreased by $0.6 million for the six months ended June 30, 2024 compared to the same period in 2023 due to a reduction in royalties earned related to sales of ERVEBO®.

Research and Development Expenses . Research and development expenses increased by $1.5 million for the six months ended June 30, 2024 compared to the same period in 2023 primarily due to increases of $2.0 million in licensing expense driven by the Ammonett milestone payment in March 2024, $0.6 million in clinical trial expenses and $0.3 million in consulting expenses, offset by decreases of $1.0 million in contract manufacturing expenses and $0.4 million in personnel-related expenses.

General and Administrative Expenses. General and administrative expenses decreased by $1.0 million for the six months ended June 30, 2024 compared to the same period in 2023 primarily due to decreases of $0.3 million in licensing expenses, $0.3 million in travel expenses, $0.2 million in consulting expenses, $0.1 million in personnel-related expenses and $0.1 million in other expenses.

Other Income, net. Other income, net decreased by $0.7 million for the six months ended June 30, 2024 compared to the same period in 2023 primarily due to a decrease in interest income driven by a decrease in short-term investments.

Liquidity and Capital Resources

We have historically devoted substantially all of our efforts toward research and development and have never earned revenue from commercial sales of our products. We expect to continue to incur additional substantial losses in the foreseeable future as a result of our research and development activities, including preparing for and conducting our LUM-201 Phase 3 trial. As of June 30, 2024, we had approximately $16.8 million of cash and cash equivalents. Our accumulated deficit as of June 30, 2024 was approximately $179.5 million. Given our current development plans and cash management efforts, we anticipate our cash resources will be sufficient to fund operations into the first quarter of 2025. However, based on our current cash forecast and our dependence on our ability to obtain additional financing to fund our operations in advancing our PGHD program into a Phase 3 trial, we concluded that our available cash and cash equivalents as of June 30, 2024 will not be sufficient to fund our operations for at least 12 months from the filing date of this Quarterly Report, and thus substantial doubt exists as to our ability to continue as a going concern.

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

We will require substantial additional capital beyond our current balance of cash and cash equivalents to fund our Phase 3 trial and our operations beyond the first quarter of 2025. We estimate the capital needed to fund our current operations and the PGHD program through the fourth quarter of 2026 will be approximately $85.0 million to $100.0 million. We plan to finance our operations and our Phase 3 trial through the sale of additional equity or debt securities, a credit facility or one or more strategic alliances. The sale of additional equity or convertible debt securities will likely result in substantial ownership dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to further reduce the scope of, delay or eliminate some or all of our planned research and development activities or to sell or liquidate our assets, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our common stock.

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

- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the scope, progress, results, and costs of clinical trials for our product candidates, and discovery and development activities related to new product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;

- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales, facilities, and distribution costs;
- the cost of manufacturing our product candidates and any products we commercialize;
- whether, and to what extent, we are required to repay our outstanding government provided loans;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- changes in domestic and global business or macro-economic conditions, including any further adverse impacts from the COVID-19 pandemic or military conflict, resulting labor shortages, supply chain disruptions, and inflation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

On December 30, 2020, we entered into a Controlled Equity Offering ^{SM} Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as agent (the "Agent"), pursuant to which we may offer and sell from time to time through the Agent up to $50.0 million of shares of our common stock (the "Shares"). The offering and sale of the Shares has been registered under the Securities Act. Under the Sales Agreement, the Agent may sell the Shares by any method permitted by law and deemed to be an "at-the-market" offering as defined in Rule 415(a)(4) promulgated under the Securities Act, including sales made directly on or through the Nasdaq, on any other existing trading market for the Shares, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices and/or any other method permitted by law. We will notify the Agent of the number of Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Shares that may be sold in any one day and any minimum price below which sales may not be made. We intend to use the net proceeds from this offering for working capital and general corporate purposes, which include, but are not limited to, funding our Phase 3 clinical trial for LUM-201 and evaluating and pursuing development opportunities for our product candidate into potential additional indications. We may also use a portion of the net proceeds to invest in future strategic transactions to expand and diversify our product pipeline through the acquisition or licensing of product candidates or technologies that are complementary to our own. We will pay the Agent a commission of up to 3.0% of the gross sales price of the Shares sold through it under the Sales Agreement. In addition, we have agreed to reimburse certain expenses incurred by the Agent in connection with the offering. The Sales Agreement may be terminated by the Agent or by us at any time upon notice to the other party, as set forth in the Sales Agreement, or by the Agent at any time in certain circumstances, including the occurrence of a material and adverse change in our business or financial condition that makes it impractical or inadvisable to market the shares or to enforce contracts for the sale of the Shares. Under our Prospectus Supplement dated August 26, 2022, we may sell up to $17.8 million of Shares under the Sales Agreement. During the year ended December 31, 2023, we sold an aggregate of 181,700 shares under the Sales Agreement, for proceeds of approximately $0.7 million. No shares were issued under the Sales Agreement during the six months ended June 30, 2024.

So long as our public float is less than $75.0 million, we will be subject to the restrictions set forth in General Instruction I.B.6 to Form S-3, which limit our ability to conduct primary offerings under a Form S-3 registration statement, including with respect to issuances under our at-the-market program under the Sales Agreement. Under such limitations, we may not sell, during any 12-month period, securities on Form S-3 having an aggregate market value of more than one-third of our public float. As of July 26, 2024, our public float calculated in accordance with General Instruction I.B.6 of Form S-3 was $11.9 million.

Cash Flows

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

	Six Months Ended June 30,	
	2024	**2023**
Net cash used in operating activities	$ (19,274)	$ (15,882)
Net cash provided by (used in) investing activities	1,000	(1,380)
Net cash used in financing activities	(5)	(883)
Net decrease in cash and equivalents	$ (18,279)	$ (18,145)

For the six months ended June 30, 2024 and 2023, our operating activities used cash of $19.3 million and $15.9 million, respectively. The increase in cash used was primarily due to increases of $1.7 million in losses from operations and $1.7 million in the change in working capital.

For the six months ended June 30, 2024 and 2023, our investing activities provided cash of $1.0 million and used cash of $1.4 million, respectively. The change is due to $1.0 million in maturities of short-term investments during the six months ended June 30, 2024 compared to $5.0 million in maturities of short-term investments offset by $6.4 million of cash used for purchases of short-term investments during the six months ended June 30, 2023.

For the six months ended June 30, 2024 and 2023, our financing activities used net cash of $5,000 and $0.9 million, respectively. The decrease was primarily due to $0.9 million in cash paid for common stock repurchases during the six months ended June 30, 2023.

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, 2024 and December 31, 2023, we had cash, cash equivalents and short-term investments of $16.8 million and $36.1 million, respectively, consisting primarily of money market funds and U.S. government and agency securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. During 2023, the Federal Reserve continued to increase rates to a target range of 5.25% to 5.50%. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, an immediate 10% change in interest rates would not have had a material effect on the fair market value of our portfolio as of June 30, 2024 and December 31, 2023.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer have concluded, based on an evaluation of our disclosure controls and procedures (as defined in the 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, 2024, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

In connection with the evaluation of our internal control over financial reporting that occurred during the quarter ended June 30, 2024, 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.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

SUMMARY OF RISK FACTORS

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

Risks Related to our Financial Condition and Capital Requirements

- We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial and increasing losses for the foreseeable future. We have only one product candidate and no commercial sales, which, together with our limited operating history, makes it difficult to evaluate our business and assess our future viability.
- We currently have no source of product revenue and may never become profitable.
- We will need to raise substantial additional funds over the next few months to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs, including our LUM-201 Phase 3 Trial, and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause substantial dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates and technologies.
- We are considering strategic alternatives in an attempt to maximize stockholder value, including financings, strategic alliances, acquisitions, out-licenses, or the possible sale of the Company. We may not be able to identify or consummate any suitable strategic alternatives.
- We might not be able to continue as a going concern.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.
- Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code").

Risks Related to the Development and Commercialization of our Product Candidate

- Data from our clinical trials may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- As an organization, we have never conducted a Phase 3 clinical trial or submitted a New Drug Application (an "NDA") before, and may be unsuccessful in doing so for LUM-201. We will need to raise substantial additional capital to fund our Phase 3 trial.
- Our success depends heavily on the successful development, regulatory approval and commercialization of our only product candidate, LUM-201. If we do not obtain approval of the Phase 3 trial design we plan to propose to the FDA and are required to conduct additional or different trials than we are anticipating, this could delay our clinical development timeline, reduce the likelihood of achieving the required primary endpoint for a Phase 3 trial and increase the amount of time and expense required for regulatory approval, if any.
- The analysis that supports our basis for pursuing development of LUM-201 for PGHD is derived from data from three clinical trials conducted by Merck in the 1990s, and a post-hoc analysis of one of the trials. Various issues relating to such trials and analysis could materially adversely impact our LUM-201 clinical trial design and our future development plans.
- Because the results of preclinical testing or earlier clinical trials are not necessarily predictive of future results, LUM-201 may not have favorable results in later clinical trials or receive regulatory approval.

- If we make changes to our product candidate, additional clinical trials may be required resulting in additional costs and delays.
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Risks Related to the Operation of our Business

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

Risks Related to our Intellectual Property

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

Risks Related to Government Regulation

- The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of our product candidates.
- Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.
- Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.
- Healthcare reform measures could hinder or prevent our product candidates' commercial success.
- Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings. If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Risks Related to Ownership of Our Common Stock

- The trading price of our common stock has been highly volatile, and could decline significantly.
- The holdings of our stockholders may be substantially diluted, and the prices of our securities may decrease, by future issuances of securities by us.
- Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.
- Our amended and restated bylaws ("Bylaws") designate the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum.
- We do not anticipate that we will pay any cash dividends in the foreseeable future.

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

RISK FACTORS

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

Risks Related to our Financial Condition and Capital Requirements

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We do not have any products approved for sale, and we are currently focused on developing our product candidate, LUM-201. Evaluating our performance, viability or future success will be more difficult than if we had a longer operating history or approved products on the market. We continue to incur significant research and development and general and administrative expenses related to our operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. We have incurred significant operating losses in each year since our inception and expect to incur substantial and increasing losses for the foreseeable future. As of June 30, 2024, we had an accumulated deficit of $179.5 million.

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

- continue the research and development of our product candidate, LUM-201, and any future product candidates;
- pursue clinical trials of LUM-201, including our planned Phase 3 clinical trial;
- seek to in-license additional product candidates and incur any future costs to develop these product candidates;
- seek regulatory approvals for LUM-201 and any future product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize LUM-201 or any future product candidates if they obtain regulatory approval, including process improvements in order to manufacture LUM-201 or any future product candidates at commercial scale; and
- enhance operational, financial and information management systems and hire more personnel, including personnel to support development of LUM-201 and any future product candidates and, if a product candidate is approved, its commercialization efforts.

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

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

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

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

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

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

We will need to raise substantial additional funds over the next few months to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs, including our LUM-201 Phase 3 Trial, and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause substantial dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates and technologies.

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

- the rate of progress and cost of our clinical trials, including our planned Phase 3 clinical trial for LUM-201;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;

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

We do not have any material committed external source of funds or other support for our planned development efforts. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. Additional financing may not be available to us when we need it or such additional financing may not be available on favorable terms. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to LUM-201 or any potential future product candidates, technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be substantially diluted, and the terms of these securities may include liquidation or other preferences that adversely affect its stockholders' rights. For example, in December 2020, we entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as agent (the "Agent"), pursuant to which we may offer and sell from time to time through the Agent up to $50.0 million of shares of our common stock from time to time in "at-the-market" offerings. During the year ended December 31, 2023, we sold an aggregate of 181,700 shares under the Sales Agreement, for proceeds of approximately $0.7 million. No shares were sold under the Sales Agreement during the six months ended June 30, 2024. 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. We have taken certain steps to delay or reduce the scope of our research programs and limit our operations until we are able to raise additional funding. If we are unable to obtain adequate financing when needed, we may have to further delay, reduce the scope of, or suspend our planned Phase 3 clinical trial for LUM-201 or one or more of our other clinical trials or research and development programs or our commercialization efforts and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our common stock.

We are considering strategic alternatives in an attempt to maximize stockholder value, including financings, strategic alliances, acquisitions, out-licenses, or the possible sale of the Company. We may not be able to identify or consummate any suitable strategic alternatives.

We are considering various strategic alternatives that may be available to us in an attempt to maximize stockholder value, including financings, strategic alliances, acquisitions, out-licenses, or the possible sale of the Company. We currently have no agreements or commitments to engage in any specific strategic transactions, and our exploration of various strategic alternatives may not result in any specific action or transaction. To the extent that these efforts result in a transaction, our business objectives may change depending upon the nature of the transaction. There can be no assurance that we will enter into any transaction as a result of our efforts. Furthermore, if we determine to engage in a strategic transaction, we cannot predict the impact that such strategic transaction might have on our operations or stock price. We also cannot predict the impact on our stock price if we fail to enter into a transaction.

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

Our unaudited condensed consolidated financial statements as of June 30, 2024 have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements also do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that

might be necessary if we are unable to continue as a going concern. As of June 30, 2024, we had approximately $16.8 million of cash and cash equivalents, and an accumulated deficit of approximately $179.5 million. Based on our current cash forecast and dependence on our ability to obtain additional financing to fund our operations in advancing our PGHD program into a Phase 3 trial, we concluded that our available cash and cash equivalents as of June 30, 2024 will not be sufficient to fund our operations for at least 12 months from the filing date of this Quarterly Report, and thus substantial doubt exists as to our ability to continue as a going concern. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

Our plan is to raise additional equity or financing to fund our future operations. While we are seeking additional financing and evaluating financing alternatives to meet our cash requirements for the next 12 months, there can be no assurances that, in the event that we require additional financing, such financing will be available on terms that are favorable to us, or at all. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current stockholders may experience substantial dilution. We have taken certain steps to delay or reduce the scope of our research programs and limit our operations until we are able to obtain additional funding. If we are unable to raise additional funding to meet our working capital needs in the future, then we may be forced to further delay or reduce the scope of our research programs and/or limit or cease our operations and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our common stock.

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

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

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

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

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

Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Code.

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

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

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

Based on subsequent analyses, we did not experience a Section 382 ownership change from March 19, 2020 through December 31, 2022. We may have experienced ownership changes within the meaning of Section 382 since December 31, 2022, however, we have not conducted further analysis since such date. Additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders.

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

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

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

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

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

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

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

Our effective income tax rate, as well as our relative domestic and international tax liabilities, will depend in part on the allocation of any future income among different jurisdictions. In addition, various factors may have favorable or unfavorable effects on our effective income tax rate in individual jurisdictions or in the aggregate. These factors include whether tax authorities agree with our interpretations of existing tax laws, any required accounting for stock options and other stock-based compensation, changes in tax laws and rates (including the recently enacted U.S. federal income tax law changes), our future levels of research and development spending, changes in accounting standards, changes in the mix of any future earnings in the various tax jurisdictions in which we may operate, the outcome of any examinations by the U.S. Internal Revenue Service or other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings. For example, the current administration has proposed tax reform legislation to increase the U.S. corporate income tax rate, increase U.S. taxation of international business operations and impose a global minimum tax, which could result in increased marginal corporate tax rates. A number of countries, as well as organizations such as the Organization for Economic Cooperation and Development, support the global minimum tax initiative. Such countries and organizations are also actively considering changes to existing tax laws or have proposed or enacted new laws that could increase our tax obligations in countries where we do business or cause us to change the way we operate our business. The effect on our income tax liabilities resulting from the above-mentioned factors or other factors could have a material adverse effect on our results of operations.

Risks Related to the Development and Commercialization of our Product Candidate

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

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

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

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

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

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

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

We cannot commercialize LUM-201 or any future product candidates in the United States without first obtaining regulatory approval for the product from the FDA, nor can we commercialize LUM-201 or any future product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. The FDA approval process typically takes years to complete and approval is never guaranteed. Before obtaining regulatory approvals for the commercial sale of LUM-201 for a target PGHD indication or any future product candidates, we generally must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical trials that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. We are pursuing the same regulatory pathway for LUM-201 followed by most of the approved rhGH products and long-acting GH products under development with LUM-201 focused on a subset of previously diagnosed PGHD patients. We intend to study treatment naïve patients by conducting a Phase 3 clinical trial with a primary endpoint of 12 month mean height velocity that is intended to support regulatory approval. We plan to propose to the FDA a single Phase 3 study, which we believe has the potential to be registrational, that will be a double-blinded, placebo-controlled clinical trial with a 2:1 randomization in approximately 150 patients for 12 months, with the placebo-controlled portion of the trial for six months. Advanced planning for this trial is underway, and we expect to finalize design details following a Type C meeting with the FDA in the third quarter of 2024 and to be in position to initiate this trial in the second quarter of 2025. The FDA may not accept our Phase 3 trial design proposal and may require us to conduct the placebo-controlled portion of the trial for 12 months, which we believe would present significant enrollment challenges. The FDA may also require us to revert to a study with an active comparator arm with a non-inferiority margin or another trial design, or require us to conduct additional well-controlled clinical investigations, any of which could increase the amount of time and expense required for our Phase 3 trial and/or reduce the likelihood of achieving the required primary endpoint in a Phase 3 clinical trial. The FDA may also disagree with our interpretation of data or may require that we develop and obtain marketing authorization for the Predictive Enrichment Marker (PEM) test, which is used to identify patients who are responsive to LUM-201. If FDA determines that the PEM test is important for ensuring the safe and effective use of our product candidate, FDA's approval of LUM-201 may be contingent upon the successful development of the PEM test. Based on the clinical data, if FDA limits our proposed indication for LUM-201, such as narrowing the indication to PGHD patients who are PEM positive, our anticipated market share may be significantly reduced.

If we are required to conduct additional or different trials than we are anticipating or that 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 OraGrowthH210 Trial do not correlate to 12 month mean height velocities that we ultimately observe in any Phase 3 clinical trial that we may conduct, LUM-201 may not achieve the required primary endpoint in the Phase 3 clinical trial, and LUM-201 may not receive regulatory approval. Moreover, obtaining regulatory approval for marketing of LUM-201 in one country does not ensure we will be able to obtain regulatory approval in other countries, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

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

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

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

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

The probability of the OraGrowtH210 Trial succeeding is highly dependent on the adequacy of the trial design. In designing such trial, we reviewed data and analysis from three studies on LUM-201 completed by Merck in the 1990s (the "Merck Trials") and we incorporated the results of our analysis of Merck's clinical data into the design of the OraGrowtH210 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 OraGrowtH210 Trial results;
- two of the Merck Trials were discontinued prior to completion due to lack of efficacy;
- one of the Merck Trials changed the formulation of the drug part way through the treatment naïve patient trial and for the other previously-treated patient trial the formulation change was for the entire trial, and the changed formulation was subsequently determined to have 30% to 40% less bioavailability;
- certain relevant information from the Merck Trials, including some of the source documentation for the Merck Trials, may not have been made available to us and so could not be referenced for our analysis and OraGrowtH210 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 OraGrowtH210 Trial design could have caused such post-hoc analysis to be unreliable.

As a result of such factors, among others, there could be flaws in the design of the OraGrowthH210 Trial that could cause it to fail, which would materially adversely impact our business, future development plans, and prospects.

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

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

There can be no assurance that LUM-201 will not exhibit new or increased safety risks in the OraGrowthH210 Trial compared to the previously conducted Merck Trials or in our planned Phase 3 clinical trial. Trials in additional indications may not be successful or may exhibit new or increased safety risks. While the topline Phase 2 results of our OraGrowthH210 Trial were encouraging, there was an imbalance in the baseline characteristics of the control arm and our final results may be materially different. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many other companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the marketing of their products.

In addition, while we are planning to move forward with the 1.6 mg/kg/day dose of LUM-201 based on the topline Phase 2 data that we released on November 7, 2023, this may not be the optimal dose for LUM-201 and we may incur additional costs or delays if we subsequently conclude there is a more optimal dose or if the FDA requires us to perform additional analysis regarding the optimal dose. Even if an optimal dose is established in one indication, different doses may be optimal in other indications requiring additional clinical trials to determine such optimal dosing.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

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

We have an ongoing research program to investigate potential opportunities to improve the potency, efficacy and/or safety profile of our product candidate through modifications to its formulation or chemical composition. This research program is part of a broader technology transfer program to establish manufacturing capacity to support our future clinical efforts. Under this technology transfer program, while the process is unlikely to produce identical results, we are working to ensure that the resultant product is equal to or better than the product made or acquired by our licensor. These efforts may not be successful. If a new formulation or composition appears promising, we may decide to undertake clinical development of such formulation or composition even if our existing product candidate has shown acceptable safety and efficacy in clinical trials. The nature and extent of additional clinical trials that might be required for a new formulation or composition would depend on many factors. Material changes to product candidates, including changes in the methods of manufacturing, carry the risk that they will not achieve consistent purity, identity, quality, efficacy and results. Any of these changes could cause our product candidate to perform differently and could affect planned or other clinical trials conducted with product candidates produced using the modified manufacturing methods, materials, and processes. This could delay completion of clinical trials and could require non-clinical or clinical bridging and comparability studies, which could increase costs, delay approval of our product candidate and jeopardize our ability to commercialize our product candidate, if approved. If we were to decide to pursue clinical development of a new formulation or composition, we would incur additional costs and the timeline for potential commercialization would be delayed. There can be no assurance that any new formulation or composition would prove to be safe or effective or superior to our existing product candidate. Any delay in commercialization of a new formulation or composition may adversely affect our competitive position.

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

Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle, including by allowing IND applications to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. Furthermore, our resource allocation decisions and our decisions about whether and how to develop or commercialize any particular product candidate may be based on evaluations of the scientific and commercial potential or target market for the product candidate that later prove to be materially inaccurate. If we enter into collaborations, licensing or other royalty arrangements to develop or commercialize a particular product candidate, we may relinquish valuable rights to that product candidate in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

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

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

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

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

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

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

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

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

We have identified several aspects of the OraGrowthH210 Trial protocols that could potentially delay or prevent our ability to receive regulatory approval or commercialize LUM-201. The OraGrowthH210 Trial will test doses of LUM-201 that are equal to, and two and four times higher than, the highest doses tested in the pediatric multiple dose Merck Trials. These higher doses were never tested in adults or children in a multiple dose trial in the Merck Trials and, even if the trials are able to show that such higher doses increase efficacy, such higher doses may not be as safe as the doses tested in the Merck Trials. As a result, frequent safety assessments may be required during the trial.

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

as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize LUM-201 or any future product candidates, including the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Assuming the success of our clinical trials, we anticipate seeking regulatory approval for LUM-201 in all major jurisdictions for treatment of a subset of PGHD patients based on a once daily weight-based dosing regimen. It is possible though that the FDA, the EMA, or regulatory agencies in other countries may not consider the results of our clinical trials to be sufficient for approval of LUM-201 for this indication. In general, the FDA suggests that sponsors complete two adequate and well-controlled clinical trials to demonstrate effectiveness because a conclusion based on two persuasive trials will be more compelling than a conclusion based on a single trial. Even though we achieved favorable results in the OraGrowthH210 Trial or if we achieve favorable results in our planned Phase 3 clinical trial, considering that LUM-201 is a new chemical entity the FDA may nonetheless require that we conduct additional clinical trials, possibly using a different clinical trial design.

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

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

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

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

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

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

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

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

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

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

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

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

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

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming

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

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

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

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

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

In addition to the currently approved and marketed daily rhGH therapies, there are a variety of experimental therapies and devices that are in various stages of clinical development by companies already participating in the rhGH market as well as potential new entrants, principally Novo Nordisk, Genexine Inc. and OPKO Health, Inc. (in collaboration with Pfizer). During the fourth quarter of 2021, OPKO Health, Inc.’s NGENLA® (somatrogon), a once-weekly injectable long-acting human growth hormone molecule, was granted regulatory approvals in Europe, Japan, Australia and Canada and became commercially available in Canada during the first quarter of 2022.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Pursuant to the terms of our settlement agreement with The Avicena Group, Inc. and its Chief Executive Officer, we have agreed not to, among other things, develop, commercialize, market, sell, license, transfer or otherwise exploit any substance, therapeutic, diagnostic or other methodology in the dermatological field or the fields of Parkinson's, Huntington's and ALS diseases through November 19, 2037. As a result, we may be limited in our ability to develop or collaborate on products in those fields, and we could miss valuable future opportunities thus potentially adversely affecting our financial results, business and business prospects.

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

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

Agreement. For example, lack of familiarity with the viral vaccine and potential adverse events associated with vaccination may adversely affect physician and patient perception and uptake of such product. Furthermore, there are no assurances that the vaccine will be approved for inclusion in government stockpile programs, which may be material to the commercial success of the product candidate, either in the United States or abroad. Finally, in certain cases, our obligations to pay royalties to the Public Health Agency of Canada ("PHAC") may exceed the royalties we receive from Merck.

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

We have in the past and currently supply indoximod in support of Phase 2 investigator-initiated clinical trials. Our Ebola vaccine product candidate was studied in clinical trials in West Africa. Additionally, we have agreed to supply NLG919 and NLG802 for future investigator-initiated clinical trials. We are also in a clinical collaboration with Massachusetts General Hospital to evaluate oral LUM-201 in nonalcoholic fatty liver disease. We may continue to supply and otherwise support similar trials in the future. However, because we are not the sponsors of these trials, we do not control the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment, and, as a result, are subject to risks associated with the way these types of trials are conducted, in particular should any problems arise. These risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data.

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

Economic, political and social conditions, including supply chain disruptions, inflation, and clinical site closures, resulting from military conflicts, including Russia's invasion of Ukraine and the conflicts in the Middle East, could materially disrupt our clinical trials, increase our costs and may disrupt planned clinical development activities. For example, we rely on suppliers in Germany, and to the extent the military conflict between Ukraine and Russia adversely impacts the ability of our suppliers to produce and distribute the supplies we need for our OraGrowthH210 Trial, or such distribution cannot be done on a timely basis, the timing for completing our OraGrowthH210 Trial may be adversely impacted. In addition, the United States, United Kingdom and European Union governments, among others, have instituted various sanctions and export-control measures in response to the invasion, including comprehensive financial sanctions, targeted at Russia or designated individuals and entities with business interests and/or government connections to Russia or those involved in Russian military activities. Governments have also enhanced export controls and trade sanctions targeting Russia's imports of goods. The duration and intensity of this conflict and its economic impact on our European operations is uncertain at this time, but it is possible that our business, results of operations and financial condition could be materially and adversely affected.

Risks Related to the Operation of our Business

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

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

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

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

As of June 30, 2024, we had 33 employees. As we plan and undertake our Phase 3 clinical trial following the favorable data read-out of our OraGrowthH210 Trial which we announced on November 7, 2023, subject to obtaining required additional funding, we expect to experience significant growth in the number of our employees and the scope of our operations,

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

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

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

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

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

If we obtain approval to commercialize LUM-201 or if we rely on suppliers or have operations 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.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in

Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We currently have limited experience in, and we do not own facilities for, clinical-scale manufacturing of our sole product candidate, LUM-201. We relied upon an existing supply of LUM-201 API obtained in connection with the APA by and between Lumos and Ammonett and the Lumos Merck Agreement and such supply was sufficient for our OraGrowthH210 Trial. In preparation and anticipation of our Phase 3 clinical trial, we have manufactured a small batch of API and LUM-201 drug product. However, we have not completed a scale up manufacturing of LUM-201 and will need additional supply of LUM-201 to conduct our Phase 3 trial. We currently intend to rely upon a single third-party CMO to manufacture and supply drug product for our clinical trials of LUM-201. The manufacture of pharmaceutical products in compliance with the FDA's cGMP requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including production shortages resulting from events affecting raw material supply or manufacturing capabilities, difficulties with production costs, yields, and quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements and foreign regulations. If any manufacturer contracted by us were to encounter any of these difficulties or otherwise fail to comply with its obligations to us or under applicable regulations, our ability to provide study drugs in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

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

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

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

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

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

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

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may also adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

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

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

Risks Related to our Intellectual Property

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

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

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

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

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

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

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

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

substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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

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

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

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

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

Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

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

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

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

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

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

As we have done previously, we may need to obtain licenses from third parties to advance our research or allow commercialization of sole product candidate, and we cannot provide any assurances that third-party patents do not exist that might be enforced against LUM-201 or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or

commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation to pay royalties and/or other forms of compensation.

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

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

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

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

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

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

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

- the patents of others may have an adverse effect on our busines s.

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

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

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

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

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

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

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

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

Risks Related to Government Regulation

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

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

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

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

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

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

If LUM-201 or any future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain regulatory approval, our business and results of operations will be materially and adversely harmed. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product's commercial potential

Further, the FDA's or other ex-U.S. regulators' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If the Supreme Court reverses or

curtails the Chevron doctrine, which gives deference to regulatory agencies in litigation against FDA and other agencies, more companies may bring lawsuits against FDA to challenge longstanding decisions and policies of FDA, which could undermine FDA's authority, lead to uncertainties in the industry, and disrupt FDA's normal operations, which could delay FDA's review of our marketing applications. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

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

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

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

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

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

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

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

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

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

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

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

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

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

There have been legislative and judicial efforts to repeal, replace, or change some or all of the PPACA. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the PPACA, dismissing the case without specifically ruling on the constitutionality of the PPACA. Accordingly, the PPACA remains in effect in its current form. It is unclear how future litigation and healthcare measures promulgated by the Biden administration will impact the implementation of the PPACA, our business, financial condition and results of operations. Litigation and legislation over the PPACA may continue, with unpredictable and uncertain results. Complying with any new legislation or reversing changes implemented under the PPACA could be time-intensive and expensive, resulting in a material adverse effect on our business. We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend

proposals for spending reductions to Congress, including aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, starting in 2013, which will remain in effect through 2032, unless additional Congressional action is taken. In January 2013, President Obama signed into law the ATRA, which delayed for another two months the budget cuts mandated by the sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We cannot predict whether any additional legislative changes will affect its business.

There have been several recent Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in January 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace, which also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. Under the American Rescue Plan Act of 2021, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs has been eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material adverse impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear and could have a material adverse effect on our business, financial condition, and results of operations. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. Additionally, FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida.

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

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

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

respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical trials before completion or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

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

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

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

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like ours which provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal transparency requirements under the Sunshine Act requires, in part, applicable manufacturers of drugs, devices, biologics and medical supplies, for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, to report annually to the CMS information related to certain payments and other transfers of value made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- HIPAA prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH and their implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous and related state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state laws require biotechnology companies to report information on the pricing of certain drug products, and certain state and local laws require the registration of pharmaceutical sales representatives. State and foreign laws also

govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection, use, and other processing of health data relating to individuals in the European Union is governed by the General Data Protection Regulation (the "GDPR"), which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union. The United Kingdom has implemented legislation similar to the GDPR, including the UK Data Protection Act and legislation similar to the GDPR referred to as the UK GDPR, which provides for fines of up to the greater of 17.5 million British Pounds or 4% of a company's worldwide turnover, whichever is higher. We cannot fully predict how the Data Protection Act, the UK GDPR, and other United Kingdom data protection laws or regulations may develop in the medium to longer term nor the effects of divergent laws and guidance regarding how data transfers to and from the United Kingdom will be regulated. We may find it necessary or otherwise appropriate to modify our policies and practices in efforts to comply with the GDPR and data protection laws in European Union member states and the United Kingdom, and may incur liabilities, expenses, costs, and other operational losses under in connection with any measures we take to comply with them.

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

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

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

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

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

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

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

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

- The federal Physician Payments Sunshine Act, and its implementing regulations require, in part, applicable manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS, information related to payments and other transfers of value made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as information related to ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

- our ability to raise additional capital when needed and the pricing and other terms of such financing, including the substantial amount of ownership dilution that will result from such financing;
- 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;
- new products, product candidates or new uses for existing products introduced or announced by our strategic collaborators, or our competitors, and the timing of these introductions or announcements;
- variations in the level of expenses related to any of our product candidates or clinical development programs, including those relating to the timing of invoices from, and other billing practices of, our clinical research organizations and clinical trial sites;
- expenses related to, or our ability or perceived ability to secure, an adequate supply of any future products approved for commercial sale;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures and capital commitments;
- the commercial or clinical success or failure, or perceived success or failure, of our collaborators, including Merck;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- media attention, or changes in media attention, given to cancer and cancer treatment, the recent Ebola epidemic and efforts to develop treatments and vaccines for Ebola, or any other condition or disease that our product candidates are being developed to treat;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- the financial projections we may provide to the public, and any changes in these projections or our failure to meet these projections;
- deviations from securities analysts' estimates or the impact of other analyst rating downgrades by any securities analysts who follow our common stock;
- other events or factors, including those resulting from public health crises such as pandemics, political uncertainty, war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation has been, and in the future may be, brought against us, which may result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

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

We will require substantial additional capital beyond our current balance of cash, cash equivalents and short-term investments to fund our Phase 3 trial and our operations beyond the end of 2024. Any such required additional capital may not be available on reasonable terms, if at all. We have taken certain steps to delay or reduce the scope of our research programs and limit our operations until we are able to obtain additional capital. If we are unable to obtain substantial additional financing, we may be required to further reduce the scope of, delay or eliminate some or all of our planned research and development activities including our planned Phase 3 trial of LUM-201 or to sell or liquidate our assets, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our common stock. To raise required additional capital, we expect to issue additional shares of common stock, preferred stock, restricted stock units (RSUs), or securities convertible into or exchangeable for shares of our common stock. In December 2020, we entered into the Sales Agreement with the Agent, pursuant to which we may offer and sell from time to time through the Agent up to $50.0 million of shares of our common stock from time to time in "at-the-market" offerings. During the year ended December 31, 2023, we sold an aggregate of 181,700 shares under the Sales Agreement, for proceeds of approximately $0.7 million. No shares were issued under the Sales Agreement during the six months ended June 30, 2024. Substantially all shares of common stock for which our outstanding stock options are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, RSUs, or securities convertible into or exchangeable for our common stock or the exercise of stock options would dilute existing investors and could adversely affect the price of our securities. In addition, such securities may have rights senior to the rights of securities held by existing investors.

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

As of June 30, 2024, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 49.1% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after June 30, 2024. These stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our Board, future issuances of our common stock or other securities, declarations of dividends on our common stock and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock. In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares may be distributed and subsequently voted.

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

Our Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on behalf of the corporation; (2) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, other employee or stockholder of the corporation to the corporation or to the corporation's stockholders; (3) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or the Bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or (4) any action asserting a claim governed by the internal affairs doctrine. This choice of forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Act, or the Exchange Act, or any claim for which the federal courts have exclusive jurisdiction.

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

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

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

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

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

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

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

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

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

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

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Not applicable.

Issuer Purchases of Equity Securities

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

Exhibit Number		Description	Incorporated By Reference			Filed or Furnished Herewith
			Form	Filing Date	Number	
3.1		Amended and Restated Certificate of Incorporation filed on November 16, 2011, as amended	10-K	3/9/2021	3.1	
3.2		Amended and Restated Bylaws	8-K	9/30/2019	3.1	
4.1		Form of the Registrant's Common Stock Certificate	8-K	3/18/2020	4.1	
10.1		Amended and Restated 2009 Equity Incentive Plan	10-Q	8/8/2019	10.1	
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.

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 2, 2024

By: /s/ Lori D. Lawley
Lori D. Lawley
Chief Financial Officer and Secretary
(Principal Financial Officer)
Date: August 2, 2024

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 2, 2024

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

EXHIBIT 31.2

CERTIFICATION

I, Lori Lawley, certify that:

1. I have reviewed this Form 10-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 2, 2024

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

EXHIBIT 32.1

CERTIFICATION

Pursuant to the requirements set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Richard J. Hawkins, Chief Executive Officer of Lumos Pharma, Inc. (the "Company"), and Lori Lawley, Chief Financial Officer 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, 2024, 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 2, 2024.

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

By: /s/ Lori Lawley
Lori Lawley
Chief Financial Officer
(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."