UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

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

March 7, 2024 Date of Report (date of earliest event reported)

LUMOS PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware

001-35342

42-1491350

(State or other jurisdiction of incorporation or organization)

(Commission File Number)

(I.R.S. Employer Identification No.)

4200 Marathon Blvd., Suite 200
Austin, Texas 78756
(Address of Principal Executive Offices)
(512) 215-2630
Registrant's telephone number, including area code

Che	ck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):	
	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)	
П	Salisiting material pursuant to Pula 14a 12 under the Evahance Act (17 CEP 240 14a 12)	

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

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

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

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

Emerging growth company \square

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.

Item 2.02. Results of Operations and Financial Condition.

On March 7, 2024, Lumos Pharma, Inc., a Delaware corporation (the "Company"), issued a press release providing financial results for the year ended December 31, 2023 (the "Press Release").

A copy of the Press Release and the Year End 2023 Financial Results Presentation are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

The information in this Current Report, including Exhibits 99.1 and 99.2 attached hereto are furnished under Item 2.02 of this report and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

 Exhibit Number
 Description

 99.1
 Press Release, dated March 7, 2024, entitled "Lumos Pharma Reports Full Year 2023 Financial Results and Provides Clinical Development Update" Year End 2023 Financial Results Presentation

 99.2
 Year End 2023 Financial Results Presentation

 104
 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Dated: March 7, 2024

LUMOS PHARMA, INC., a Delaware corporation

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



Lumos Pharma Reports Full Year 2023 Financial Results and Provides Clinical Development Update

End of Phase 2 Meeting to Occur in Q2 2024, Initiation of LUM-201 Phase 3 Trial Expected in Q4 2024

Previously Announced Topline Data from Phase 2 OraGrowtH210 and OraGrowtH212 Trials of LUM-201 in Moderate PGHD Met All Primary and Secondary Endpoints

Pisit "Duke" Pitukcheewanont, MD, Appointed Chief Medical Officer

Conference Call Today at 4:30 PM EST

AUSTIN, TX, March 7, 2024 (GLOBE NEWSWIRE) – Lumos Pharma, Inc. (NASDAQ:LUMO), a late-stage biopharmaceutical company advancing an oral therapeutic candidate for moderate Pediatric Growth Hormone Deficiency (PGHD), today announced financial results for the year ended December 31, 2023 and provided an update on clinical and regulatory activity.

"The past year was a highly successful one for Lumos, culminating in the announcement of topline results from our Phase 2 OraGrowtH210 and OraGrowtH212 trials, which met all of their primary endpoints and provided substantial support for the advancement of LUM-201 toward a registrational Phase 3 trial in moderate PGHD," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "We expect to present full twelve-month and longer-term data in a subset of patients from these trials at a medical meeting in the second quarter of this year. Next steps for this program are also on track, with our End-of-Phase 2 Meeting with the FDA scheduled for next quarter, and preparation for our Phase 3 pivotal trial of LUM-201 well underway. We expect to be in position to initiate this registrational trial in the fourth quarter, pending positive feedback from the FDA. As evidenced by the Key Opinion Leader event we held last December, there is broad support among the pediatric endocrinology community for our novel approach to treating growth hormone disorders, and we remain confident in this asset's potential to become the first oral therapeutic for the treatment of PGHD."

Upcoming Milestones

- Full 12-month data from OraGrowtH210 Trial to be presented in Q2 2024 at major medical meeting
- End of Phase 2 Meeting to occur in Q2 2024
- · Company expects to initiate Phase 3 pivotal trial of LUM-201 in Q4 2024

Recent Highlights

- · Topline Data from Phase 2 OraGrowtH210 and OraGrowtH212 Trials of LUM-201 in PGHD Met All Primary and Secondary Endpoints
 - OraGrowtH210 results showed LUM-201 dose of 1.6 mg/kg achieved annualized height velocities (AHV) of 8.2 cm/yr at 6 months and 8.0 cm/yr at 12 months, similar to growth rates for moderate PGHD population

- Delta at 6 and 12-month AHV between optimal LUM-201 dose of 1.6 mg/kg and rhGH comparator arm was within the non-inferiority margin (< 2 cm/yr) suggested by FDA for recent approvals
- o Initial 24-month LUM-201 data from combined OraGrowtH210 and OraGrowtH212 Trials demonstrated a sustained AHV effect from Year 1 to Year 2
- OraGrowtH212 demonstrated that, with only 20% of the GH concentration of injectable rhGH, LUM-201 achieved similar AHV, illustrating the greater efficiency of LUM-201's unique pulsatile mechanism of action
- OraGrowtH210 Trial met pre-specified primary endpoint of validation of Predictive Enrichment Marker (PEM) test and secondary endpoint demonstrating 100% reproducibility of PEM-Positive classification
- No safety signal to date for LUM-201

· Pisit "Duke" Pitukcheewanont, MD Appointed Chief Medical Officer

Dr. Duke as he is known was promoted to the position of CMO effective January 1, 2024. In this role, Dr. Duke will provide his leadership in Lumos Pharma's efforts to hone its clinical and regulatory strategy and will continue to oversee medical affairs as the Company prepares to initiate a pivotal Phase 3 trial evaluating oral LUM-201 as a therapeutic for moderate PGHD.

Financial Results for the Year Ended December 31, 2023

- Cash Position Lumos Pharma ended the year on December 31, 2023, with cash, cash equivalents, and short-term investments totaling \$36.1 million compared to \$67.4 million on December 31, 2022. Cash on hand as of December 31, 2023 is expected to support operations through the third quarter of 2024.
- R&D Expenses Research and development expenses were \$22.1 million, an increase of \$4.2 million for the year ended December 31, 2023 compared to the same period in 2022, primarily due to increases of \$3.3 million in clinical trial expenses, \$0.9 million in contract manufacturing expenses, \$0.2 million in consulting expenses and \$0.2 million in other expenses, partially offset by a \$0.4 million decrease in personnel-related expenses.
- G&A Expenses General and administrative expenses were \$16.6 million, an increase of \$0.9 million for the year ended December 31, 2023 compared to the same period in 2022, primarily due to increases of \$0.5 million in personnel-related expenses, \$0.4 million in royalty expenses and \$0.1 million in travel expenses, partially offset by a \$0.1 million decrease in other expenses.
- Net Loss The net loss for the year ended December 31, 2023 was \$34.0 million compared to a net loss of \$31.1 million for the same period in 2022.
- Lumos Pharma ended Q4 2023 with 8,102,555 shares outstanding.

Conference Call and Webcast Details

The Company has scheduled a conference call and webcast for 4:30 p.m. ET today to discuss its financial results and to give an update on clinical programs. There will also be a question-and-answer session following management's prepared remarks.

Investors and the general public are invited to listen to the conference call. To access the call by phone, please click on this Registration Link, complete the form and you will be provided with dial-in details and a PIN. To avoid delays, we encourage participants to dial in to the conference call ten minutes ahead of

the scheduled start time. The webcast may be accessed through this Webcast Link and may also be found in the "Investors & Media" section of the Lumos Pharma website, under "Events & Presentations." A replay of the call will be available after the date of the call and may be accessed through the same link above or found on our website.

About Lumos Pharm

Lumos Pharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of therapeutics for rare diseases. The Company was founded and is led by a management team with longstanding experience in rare disease drug development. Lumos Pharma's lead therapeutic candidate, LUM-201, is a novel, oral growth hormone (GH) secretagogue, seeking to transform the ~\$3.4B global GH market from injectable to oral therapy. LUM-201 is currently being evaluated in multiple Phase 2 clinical studies in Pediatric Growth Hormone Deficiency (PGHD) and has received Orphan Drug Designation in both the US and EU. For more information, please visit https://lumos-pharma.com/.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of Lumos Pharma, Inc. that involve substantial risks and uncertainties. All such statements contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. A law that, in part, gives us the opportunity to share our outlook for the future without fear of litigation if it turns out our predictions were not correct.

We are passionate about our business - including LUM-201 and the potential it may have to help patients in the clinic. This passion feeds our optimism that our efforts will be successful and bring about meaningful change for patients. Please keep in mind that actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make.

We have attempted to identify forward-looking statements by using words such as "projected," "upcoming," "will," "would," "plan," "intend," "anticipate," "approximate," "expect," "potential," "imminent," and similar references to future periods or the negative of these terms. Not all forward-looking statements contain these identifying words. Examples of forward-looking statements include, among others, statements we make regarding the advancement of oral LUM-201 to Phase 3, the expected timing of trial data presentations and FDA meetings, substantial support for the advancement of LUM-201 toward a registrational Phase 3 trial in moderate PGHD, that we expect to present full twelve-month and longer-term data in a subset of patients from these trials at a medical meeting in the second quarter of this year, that next steps for this program are on track, that we expect to be in position to initiate this registrational trial in the fourth quarter, that there is broad support among the pediatric endocrinology community for our novel approach to treating growth hormone disorders, that we remain confident in this asset's potential to become the first oral therapeutic for the treatment of PGHD, that cash on hand as of December 31, 2023 is expected to support operations through the third quarter of 2024, and any other statements other than statements of historical fact.

We wish we were able to predict the future with 100% accuracy, but that just is not possible. Our forward-looking statements are neither historical facts nor assurances of future performance. You should not rely on any of these forward-looking statements and, to help you make your own risk determinations, we have provided an extensive discussion of risks that could cause actual results to differ materially from our forward-looking statements including risks related to the continued analysis of data from our LUM-201 Trials, the timing and outcome of our future interactions with regulatory authorities including our end of Phase 2 meeting with the FDA, the timing and ability of Lumos to raise additional equity capital as

needed to fund our Phase 3 Trial, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to structure our Phase 3 trial in an effective and timely manner, the ability to successfully develop our product candidate, the effects of pandemics, other widespread health problems or military conflicts including the Ukraine-Russia conflict and the Middle East conflict and other risks could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements including information in the "Risk Factors" section and elsewhere in Lumos Pharma's Annual Report on Form 10-K for the year ended December 31, 2022, as well as other reports filed with the SEC including our most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2023. All of these documents are available on our website. Before making any decisions concerning our stock, you should read and understand those documents.

We anticipate that subsequent events and developments will cause our views to change. We may choose to update these forward-looking statements at some point in the future, however, we disclaim any obligation to do so. As a result, you should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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Investor & Media Contact:

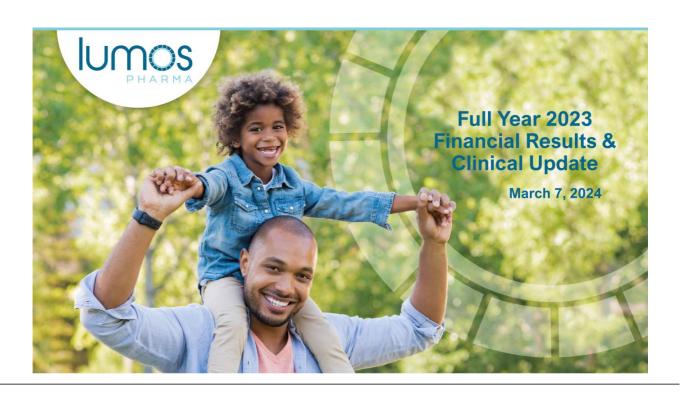
Lisa Miller Lumos Pharma Investor Relations 512-792-5454 ir@lumos-pharma.com

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

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

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

		December 31,		
	202	23		2022
Assets				
Current assets:				
Cash and cash equivalents	\$	35,078	\$	56,007
Short-term investments		999		11,352
Prepaid expenses and other current assets		3,748		4,427
Other receivables		210		223
Total current assets		40,035		72,009
Non-current assets:				
Property and equipment, net		_		53
Right-of-use asset		603		230
Total assets	\$	40,638	\$	72,292
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$	890	\$	275
Accrued expenses		5,858		6,200
Current portion of lease liability		282		233
Total current liabilities		7,030		6,708
Long-term liabilities:				
Royalty obligation payable to Iowa Economic Development Authority		6,000		6,000
Lease liability		303		_
Total liabilities		13,333		12,708
Commitments and contingencies:				
Stockholders' equity:				
Undesignated preferred stock, \$0.01 par value: Authorized shares - 5,000,000 at December 31, 2023 and 2022; issued and outstanding shares - 0 at December 31 2023 and 2022	,	_		_
Common stock, \$0.01 par value: Authorized shares - 75,000,000 at December 31, 2023 and 2022; issued shares - 8,125,728 and 8,283,708 at December 31, 2023 and 2022, respectively, and outstanding shares - 8,102,555 and 8,267,968 at December 31, 2023 and 2022, respectively		81		82
Treasury stock, at cost, 23,173 and 15,740 shares held as of December 31, 2023 and 2022, respectively		(196)		(170)
Additional paid-in capital		188,937		187,164
Accumulated deficit		(161,517)		(127,483)
Accumulated other comprehensive loss				(9)
Total stockholders' equity		27,305		59,584
Total liabilities and stockholders' equity	\$	40,638	\$	72,292





Forward Looking Statements

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We wish we were able to predict the future with 100% accuracy, but that just is not possible. Our forward-looking statements are neither historical facts nor assurances of future performance. You should not rely on any of these forward-looking statements and, to help you make your own risk determinations, we have provided an extensive discussion of risks that could cause actual results to differ materially from our forward-looking statements including risks related to the continued analysis of data from our LUM-201 Trials, the timing and outcome of our future interactions with regulatory authorities including our end of Phase 2 Trial, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to surcessfull develop our LUM-201 Trials, our ability to project future and initiate our Phase 3 trial in an effective and timely manner, any statements regarding potential enrollment timelines, the ability to successfully develop our LUM-201 Trials, our ability to surcessfully develop our LUM-201 Trials. On the widespread health problems or military conflicts including the Ukraine-Russia conflict and the Middle East conflict and other risks that could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements including information in the "Risk Factors" section and elsewhere in Lumos Pharma's Quarterly Report on Form 10-Q for the period ended September 30, 2023, as well as other reports filed with the SEC including our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. All of these documents are available on our website. Before making any decisions concerning our stock, you should read and understand those documents.

We anticipate that subsequent events and developments will cause our views to change. We may choose to update these forward-looking statements at some point in the future, however, we disclaim any obligation to do so. As a result, you should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation.

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Agenda

Welcome

· Lisa Miller, Vice President of Investor Relations

Review of Highlights & Clinical Development Program

· Rick Hawkins, Chief Executive Officer & Chairman

Financial Results

· Lori Lawley, Chief Financial Officer

Questions & Answers

- Rick Hawkins, Chief Executive Officer & Chairman
- John McKew, PhD, President & Chief Scientific Officer
- Lori Lawley, Chief Financial Officer
- · Duke Pitukcheewanont, MD, Chief Medical Officer



Management - Significant Clinical Development and Commercial Experience



Richard Hawkins Chairman & CEO Developed Growth Hormone (GH) Receptor Antagonist for Acromegaly at Sensus (sold to Pfizer), Built one of the first contract recombinant protein manufacturing facilities (Covance Biotechnology). Founder of Pharmaco, a pioneer in the contract research organization sector (merged with PPD).



John McKew, PhD President & Chief Scientific Officer Prior VP of Research at aTyr Pharma – led team advancing protein-based therapeutics for rare diseases. Former Scientific Director, NIH - National Center for Advancing Translational Science (NCATS) and Therapeutics for Rare and Neglected Diseases (TRND).



Lori Lawley, CPA Chief Financial Officer Former SVP, Finance and Controller at Lumos Pharma. Previously, SVP, Finance and Member of the Office of the CEO of NewLink Genetics. Prior to that, Senior Manager in Assurance Services at Ernst and Young.



Pisit "Duke" Pitukcheewanont, MD Chief Medical Officer Pediatric endocrinologist and Professor, Clinical Pediatrics, Keck School of Medicine, USC. President, Human Growth Foundation. Former VP Medical Affairs and VP Global Medical Ambassador & Medical Education at Ascendis Pharma; project: long-acting TransCon GH. Former Advisory Board member at Pfizer, Ipsen, Alexion, Ultragenyx, Pharmacia, Serono, others.



Aaron Schuchart, MBA Chief Business Officer Former Chief Business Officer of Aeglea BioTherapeutics. Former leadership roles in Business Development, Strategy, and Finance at Coherus Biosciences, Novartis Diagnostics/Grifols, and Amgen.



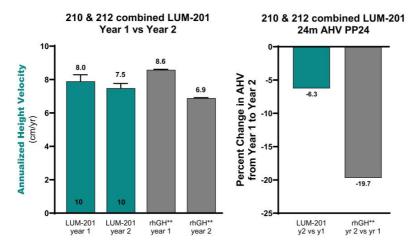
OraGrowtH Trials - Topline Phase 2 Data Highlights

OraGrowtH210 and OraGrowtH212 Phase 2 Clinical Trials

- o Met all primary and secondary endpoints
- o PEM test was reproducible and predicted response to LUM-201
- o LUM-201 restored GH secretion through increased amplitude of pulsatility and normalized IGF-1
- o LUM-201 promoted growth similar to injectable rhGH with only 20% of GH concentration levels
- o AHV of 1.6 mg/kg LUM-201 arm vs rhGH arm was within historical Phase 3 non-inferiority margins*
- o Preliminary 24-month data demonstrated sustained growth on LUM-201
- o Favorable safety profile to date

* AHV = Least Squares Mean Annualized Height Velocity, AHV values from the OraGrowtH studies are based on ANCOVA model.

LUM-201 Data Suggests Greater Durability of Response than rhGH to 24 Months lumos OraGrowtH210 & OraGrowtH212 Combined (1.6 and 3.2 mg/kg LUM-201)



Highlights

- · Preliminary data demonstrate LUM-201 AHV durable to 24 months
- More moderate year 2 AHV decline than rhGH likely due to LUM-201 restoration of GH and IGF-1 to normal levels via pulsatile secretion

AHV values from the OraGrowth studies are based on ANCOVA model (details provided on previous slides)

* At 24 months, data include a subset of subjects from OraGrowtH210 trial who met protocol criteria to continue past 12 months.

** Ranke et.al. 2010 – rhGH treated cohort of moderate GHD children; mean AHV for the moderate GHD cohorts were 8.58 cm/yr in year 1 and 6.89 cm/yr in year 2.

LUM-201 Normalizes GH Secretion in Moderate PGHD



Injectable rhGH (34 μg/kg/d) exposes patient to ~5x normal GH concentrations

Growth Hormone Concentrations (µg/kg/24 hours)

Normal healthy (IC-GH [‡])	Untreated PGHD (IC-GH [‡])	LUM-201 (Baseline GH)* LUM-201 (Treated 6M GH)*		Comparator arm rhGH 34 µg/kg/day
Zadik [†]	Zadik [†]		N = 22	
5.0 <u>+</u> 1.3	1.4 <u>+</u> 0.5	1.7 <u>+</u> 1.3 [¥]	3.3 ± 1.8 to 4.0 ± 2.1 [¥]	~20

Increasing 24-hour pulsatile secretion, LUM-201 achieves comparable growth to exogenous injectable rhGH, with only 20% of GH concentration levels

[‡] IC-GH: integrated concentration of Growth Hormone; data represent mean <u>+</u> standard deviation ^{*} GH concentrations from the combined 1.6 and 3.2 mg/kg/day cohorts of the OraGrowtH212 Trial [¥] 24-hr GH concentration for LUM-201 calculated from 12-hr data using published conversion ratios

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

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Next Steps

Upcoming Milestones

- o Full 12-month data from OraGrowtH210 Trial to be announced in 2Q 2024
 - o Additional 24-month data to be reported
- o End-of-Phase 2 meeting with FDA in 2Q 2024
 - o Supportive comprehensive data package
- o Initiation of pivotal Phase 3 program anticipated in 4Q 2024
 - o Multi-national trial design expected to be similar to recent peer trials
 - o Estimated ~200 subjects, 2:1 randomization oral LUM-201:injectable rhGH, 12 months on treatment



Lumos Pharma Financial Information as of December 31, 2023 Values in USD

	Year 2023	Year 2022
R&D Expense	\$22.1M	\$17.9M
G&A Expense	\$16.6M	\$15.7M
Net Loss	\$34.0M	\$31.1M
Cash, Cash Equivalents, and Short-Term Investments at Year-end	\$36.1M	\$67.4M
Shares Outstanding at Year-end	8,102,555	8,267,968



Cash, cash equivalents, & short-term investments to support operations through 3Q 2024, inclusive of activities related to advancing the PGHD program into Phase 3

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Investment Thesis Lead asset targeting children with growth disorders

Attractive Market Opportunity

- · Daily oral expected to be well received in GH markets
- · Market research supports rapid conversation to oral and potential expansion opportunities*



Novel Asset with **Unique MOA**

- Novel MOA takes advantage of natural physiology
- Orphan Drug Designation in US/EU and issued patents in major markets



Clear Proof of Concept

- PEM strategy de-risks patient selection, identifying likely LUM-201 responders**
- Phase 2 trials met all primary and secondary endpoints
- Consistent PK/PD and attractive safety profile to date in > 1,300 subjects studied



Focused Execution

- Full 12-month data from OraGrowtH210 Trial to be announced in 2Q 2024
- End-of-Phase 2 meeting with FDA in 2Q 2024 to review Phase 3 program
- Initiation of Phase 3 trial anticipated 4Q 2024



Potential for 1st oral therapeutic to disrupt injectable market for GHD

* Initial Primary Research of PGHD Market conducted for Lumos by Triangle Insights

** PEM (Predictive Enrichment Marker) strategy consists of screening for PEM+ PGHD patients = Baseline IGF-1 > 30 ng/ml & Peak stimulation GH ≥ 5 ng/ml from single oral dose of LUM-201