



## Lumos Pharma Reports Second Quarter 2024 Financial Results and Provides Clinical Development Update

Aug 1, 2024

*Following Positive End of Phase 2 Meeting with FDA, Company Continues to Advance Plans for Phase 3 Placebo-Controlled Trial of LUM-201 in Moderate Pediatric Growth Hormone Deficiency*

*Expects to Initiate Phase 3 Trial in Q2 2025*

*Company to Host Conference Call Today at 4:30PM ET*

AUSTIN, Texas, Aug. 01, 2024 (GLOBE NEWSWIRE) -- [Lumos Pharma, Inc.](#) (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, today announced financial results for the quarter ended June 30, 2024 and provided a clinical programs update.

"Following our very positive and productive End of Phase 2 Meeting with the FDA, we've made substantial progress finalizing our proposal for a Phase 3 double-blinded, placebo-controlled clinical trial with a 2:1 randomization in approximately 150 subjects," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "Our proposed trial design is informed by the FDA's prior feedback and recognition of LUM-201's mechanism of action as a growth hormone secretagogue, as well as their acknowledgment that a placebo-controlled clinical trial design is an appropriate option for a LUM-201 Phase 3 trial. We expect to finalize design details with the FDA in the fourth quarter. We are prudently managing our current cash resources and evaluating all strategic opportunities as we advance these plans and expect to be in a position to initiate this trial in the second quarter of 2025."

"During our second quarter we were also pleased to present new analyses of data from our OraGrowthH212 Trial at ENDO 2024," continued Mr. Hawkins. "These data further characterized what we believe is LUM-201's unique ability to augment the natural pulsatile secretion of growth hormone and produce comparable growth to injectable rhGH with significantly less exposure to circulating growth hormone. Furthermore, with additional data, LUM-201 continues to demonstrate a durability of effect out to 24 months, with a more sustainable annualized height velocity than injectable growth hormone has shown in historical studies. We believe these analyses provide additional support for our planned approach to a placebo-controlled Phase 3 trial of LUM-201 in moderate PGHD."

### Strategic Update

The Company has engaged Piper Sandler & Co. to assist the Board of Directors in evaluating strategic opportunities to maximize stockholder value as the Company seeks to advance the LUM-201 platform.

### Q2 2024 Highlights

- **Company Advances Placebo-Controlled Phase 3 Trial Design Suggested by FDA**
  - At End-of-Phase 2 Meeting, FDA indicated that a placebo-controlled trial design is an appropriate option for a Phase 3 trial for LUM-201. We believe such a trial design would significantly improve the probability of success and potential for commercialization of the first oral therapy for moderate Pediatric GHD as compared to a non-inferiority study
  - Placebo-controlled pivotal trial design supported by FDA's recognition of LUM-201's mechanism of action as differentiated from injectable growth hormone therapies
  - Company continues to advance planning for Phase 3 trial, with initiation now anticipated in Q2 2025, allowing for manufacturing and characterization of LUM-201-matched placebo capsule containing mini-tablets
  - Finalization of Phase 3 trial design with FDA anticipated in Q4 2024
- **New Analyses of Phase 2 OraGrowthH212 Trial Presented in Two Posters at ENDO 2024**
  - Data from the posters further support the unique mechanism of action of oral LUM-201 and shows a correlation between the pattern of pulsatile growth hormone secretion and the growth response to LUM-201
  - [Oral LUM-201 Restores Pulsatile Growth Hormone Secretion and Growth Response in Moderate Pediatric Growth Hormone Deficiency \(PGHD\): Key Discoveries from Phase 2 of OraGrowthH212 Trial](#) (Cassorla, et al)
  - [Growth Response to Oral Growth Hormone Secretagogue LUM-201 in Children with Moderate GH Deficiency \(GHD\) is Dependent on the Pattern of Pulsatile GH Secretion Stimulated by LUM-201](#) (Stevens, et al)

## Financial Results for Quarter Ended June 30, 2024

**Cash Position** – Lumos Pharma ended the quarter on June 30, 2024, with cash, cash equivalents, and short-term investments totaling \$16.8 million, as compared to \$36.0 million on December 31, 2023. The Company is managing cash conservatively and believes it has sufficient cash to support operations into the first quarter of 2025.

**R&D Expenses** – Research and development expenses were \$4.6 million, a decrease of \$1.4 million for the quarter 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.

**G&A Expenses** – General and administrative expenses were \$3.7 million, a decrease of \$0.5 million 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.

**Net Loss** – The net loss for the quarter ended June 30, 2024, was \$7.6 million compared to a net loss of \$8.9 million for the same period in 2023.

Lumos Pharma ended Q2 2024 with 8,123,186 shares outstanding.

## Conference Call and Webcast Details

Date: Tuesday, August 1, 2024

Time: 4:30PM ET

Dial-in: 1- 866-652-5200 or 1- 412-317-6060 (International)

Conference ID: 10191274

Dial-in registration (Available 15 minutes prior to scheduled start time): [Click Here](#)

Dial-in registration passcode: 2835283

Webcast: [Click Here](#)

Investors and the general public are invited to listen to the conference call. To avoid delays, we encourage participants to dial into the conference call ten minutes ahead of the scheduled start time. The webcast link may also be found in the "Investors & Media" section of the Lumos Pharma website, under "[Events & Presentations](#)." A replay 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 Pharma

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 ~\$4.7B 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 our finalization of design details for a Phase 3 clinical trial with the FDA in the fourth quarter of 2024 and our positioning to initiate this trial in the second quarter of 2025, that we believe new analyses provide additional support for our planned approach to a placebo-controlled Phase 3 trial of LUM-201 in moderate PGHD, that we believe the trial design would improve the likelihood of success when compared to a non-inferiority study, that cash on hand is expected to support operations into Q1 2025, the potential for LUM-201 to be the first oral therapeutic for PGHD, 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 timing and ability of Lumos Pharma to structure our Phase 3 trial in an effective and timely manner, the ability to obtain FDA approval of, initiate and advance a pivotal Phase 3 trial, as well as advance our clinical and corporate strategy in general, our ability to obtain the capital needed to fund a Phase 3 trial and other business operations, our ability to forecast and manage future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to successfully develop our product candidate 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 Annual Report on Form 10-K for the year ended December 31, 2023 and Quarterly Reports on Form 10-Q for the periods ended March 31 and June 30, 2024, as well as other subsequent reports filed with the SEC. 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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Source: Lumos Pharma, Inc.

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

	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 income:				
Unrealized loss on short-term investments	—	(6)	—	(2)
Total comprehensive loss	\$ (7,551)	\$ (8,937)	\$ (17,992)	\$ (16,279)

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

	June 30,	December 31,
	2024 (unaudited)	2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 16,799	\$ 35,078
Short-term investments	—	999
Prepaid expenses and other current assets	3,925	3,748
Income tax receivable	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	<u>4,935</u>	<u>7,030</u>
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	145	303
Total liabilities	<u>11,080</u>	<u>13,333</u>
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 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	<u>10,275</u>	<u>27,305</u>
Total liabilities and stockholders' equity	<u>\$ 21,355</u>	<u>\$ 40,638</u>



Source: Lumos Pharma, Inc.