Lumos Pharma Announces Positive End-of-Phase 2 Meeting with FDA and Reports First Quarter 2024 Financial Results

May 14, 2024

Outcome from End-of-Phase 2 Meeting Supportive of a Placebo-Controlled Phase 3 Trial

Updated 12 and 24-Month Data from Phase 2 OraGrowtH210 and OraGrowtH212 Trials Continue to Show Oral LUM-201 Achieves Significant Increase in Growth from Baseline, Durable Effect to 24 Months

Company to Host Conference Call May 15, 2024, at 8:30AM ET

AUSTIN, Texas, May 14, 2024 (GLOBE NEWSWIRE) -- Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical stage biopharmaceutical company focused on therapeutics for rare diseases, today announced the outcome from its End-of-Phase 2 meeting with the FDA, provided a clinical programs update, and reported financial results for the quarter ended March 31, 2024.

"We are pleased to announce that, earlier this quarter, we had a very productive End-of-Phase 2 meeting with the FDA," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "In this review, the FDA recognized LUM-201's unique mechanism as a growth hormone secretagogue and acknowledged the use of a placebo-controlled clinical trial design as an appropriate option for a LUM-201 Phase 3 trial. Based on the FDA's feedback, we plan to move forward with a proposal for a single Phase 3 study that will be a double-blinded, placebo-controlled clinical trial with a 2:1 randomization in approximately 150 patients. We expect to finalize design details with the FDA in the third quarter and to be in position to initiate this trial before the end of this year.

"In addition to our encouraging engagement with the FDA, we are also very pleased to share updated data from our Phase 2 OraGrowtH trials. These data continue to show that LUM-201 produces a significant increase in growth from baseline in annualized height velocity (AHV) at 6 and 12 months in per protocol analysis. Combined data also suggest durable benefit out to 24 months.

"We believe these developments have positioned us to advance LUM-201 toward both a Phase 3 registrational trial and potential approval of LUM-201 as the first oral therapeutic for moderate pediatric growth hormone deficiency," Rick Hawkins concluded.

Recent Highlights

- **End of Phase 2 Meeting Held with FDA**
  - FDA indicated that a placebo-controlled trial design is an appropriate option for a Phase 3 trial for LUM-201. We believe this reflects FDA's recognition of unique qualities of LUM-201's mechanism of action as a growth hormone secretagogue.
  - Proposal for a Phase 3 trial to include a 12-month double-blinded, placebo-controlled design with 2:1 randomization, ~150 patients with the placebo-controlled portion of the study lasting six months, which we believe will improve the likelihood of success when compared to a non-inferiority study.
  - Planning is ongoing, and the Company expects to initiate a Phase 3 trial of LUM-201 in Q4 2024, subject to FDA approval.
- **Updated LUM-201 Data from Combined OraGrowtH210 and OraGrowtH212 Trials**
  - Additional data continue to show durable LUM-201 treatment effect to 12 and 24 months.
  - Full 12-month data from OraGrowtH210 demonstrated LUM-201 produces significant increase in growth from baseline with AHVs of 8.2 cm/yr (N=22) and 7.6 cm/yr (N=21) at 6 and 12 months, respectively, at the 1.6 mg/kg dose vs. 4.7 cm/yr baseline growth (N=13).*
  - Full 12-month data from OraGrowtH210 continued to show durable effect to 12 months for all LUM-201 cohorts and 1.6 mg/kg/day as optimal dose to advance to Phase 3.
  - Updated combined data from OraGrowtH210 and OraGrowtH212 trials continued to demonstrate LUM-201 AHV durable to 24 months with per protocol-24M (N=12) AHV of 8.1 cm/yr and 7.3 cm/yr at 12 and 24 months, respectively.
  - More moderate year-2 decline in AHV of 9.9% for LUM-201 compared to year-2 decline in AHV of 19.7% observed in historical rhGH benchmarks likely due to LUM-201 restoration of GH and IGF-1 to normal levels via amplification of physiologic pulsatile secretion of growth hormone within the natural endocrine feedback loop.
  - Investigational safety profile continues to be favorable.
- **Data from Phase 2 OraGrowtH210 and OraGrowtH212 Trials Presented at Medical Meetings in US and Europe**
  - Pediatric Endocrinology Society (PES)
  - 10th International Congress of the Growth Hormone Research Society (GRS)
  - European Congress of Endocrinology (ECE)
  - Data presented at these medical conferences demonstrate that, by augmenting the natural pulsatile secretion of

growth hormone, LUM-201 produces comparable growth to injectable rhGH with significantly less exposure to circulating growth hormone.

- **Additional Data from Phase 2 OraGrowtH Trials to be Presented in Q2 2024**
  - Full 12-Month OraGrowtH212 data, additional analyses of OraGrowtH210 data, and updated combined 24-month data to be presented in Q2 2024
  - Two abstracts accepted for poster presentation at the Endocrine Society (ENDO) Annual Meeting

*Baseline AHV data were not required for enrollment; baseline data available for N=13 subjects.

Financial Results for Quarter Ended March 31, 2024

Cash Position – Lumos Pharma ended the quarter on March 31, 2024, with cash, cash equivalents, and short-term investments totaling $23.2 million, as compared to $36.1 million on December 31, 2023. Cash on hand is expected to support operations through Q3 2024, which is inclusive of Phase 3 planning and preparatory activities.

R&D Expenses – Research and development expenses for the quarter ended March 31, 2024, were $7.2 million, an increase of $2.9 million compared to the same period in 2023, primarily due to increases of $2.0 million in licensing expense, $0.8 million in clinical trial expenses and $0.2 million in consulting expenses, offset by a decrease of $0.1 million in personnel-related expenses.

G&A Expenses – General and administrative expenses for the quarter ended March 31, 2024, were $3.8 million, a decrease of $0.6 million compared to the same period in 2023, primarily due to decreases of $0.4 million in licensing expenses, $0.1 million in travel expenses, $0.1 million in consulting expenses and $0.1 million in other expenses, offset by an increase of $0.1 million in personnel-related expenses.

Net Loss – The net loss for the quarter ended March 31, 2024, was $10.4 million compared to a net loss of $7.3 million for the same period in 2023.

Lumos Pharma ended Q1 2024 with 8,107,121 shares outstanding.

Conference Call and Webcast Details
Date: Wednesday, May 15, 2024
Time: 8:30am ET
Dial-in: 1-877-407-9716 or 1-201-493-6779 (International)
Conference ID: 13746447
Dial-in registration (Available 15 minutes prior to scheduled start time): Click Here
Webcast: Click Here

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 that our FDA meeting was supportive of a placebo-controlled Phase 3 trial, that we expect to finalize design details with the FDA in the third quarter and to be in position to initiate this trial before the end of this year, that the data continue to show that LUM-201 produces a significant increase in growth from baseline in annualized height velocity (AHV) at 6 and 12 months in per protocol analysis, that combined data also suggest durable benefit out to 24 months, that we plan to move forward with a proposal for a Phase 3 study that will be a double-blinded, placebo-controlled clinical trial with a 2:1 randomization in approximately 150 patients, that we believe this reflects the FDA's recognition of unique qualities of LUM-201's mechanism of action as a growth hormone secretagogue, that we believe these developments have positioned us to advance LUM-201 towards a Phase 3 registrational trial and toward potential approval of LUM-201 as the first oral therapeutic for moderate pediatric growth hormone deficiency, that we believe the study design will improve the likelihood of success when compared to a non-inferiority study, that the investigational safety profile continues to be favorable, that cash on hand is expected to support operations through Q3 2024, which is inclusive of Phase 3 planning and preparatory activities, 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 Type C 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, 2023, as well as other 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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Lumos Pharma, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2024	**2023**
Revenues:		
Royalty revenue	$ 165	$ 691
Total revenues	165	691
Operating expenses:		
Research and development	7,248	4,369
General and administrative	3,779	4,357
Total operating expenses	11,027	8,726
Loss from operations	(10,862)	(8,035)
Other income and expense:		
Other income, net	263	119
Interest income	158	570
Other income, net	421	689
Net loss	$ (10,441)	$ (7,346)
Net loss per share:		
Basic and diluted	$ (1.29)	$ (0.89)
Weighted average number of common shares outstanding:		
Basic and diluted	8,104,905	8,239,941
Other comprehensive income:		
Unrealized gain on short-term investments	—	4
Total comprehensive loss	$ (10,441)	$ (7,342)

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

	March 31, 2024 (unaudited)	**December 31, 2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 23,179	$ 35,078
Short-term investments	—	999
Prepaid expenses and other current assets	4,184	3,748
Income tax receivable	181	210

Total current assets	27,544	40,035
Non-current assets:		
Right-of-use asset	534	603
Total assets	$ 28,078	$ 40,638
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 569	$ 890
Accrued expenses	3,552	5,858
Current portion of lease liability	293	282
Total current liabilities	4,414	7,030
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	225	303
Total liabilities	10,639	13,333
Commitments and contingencies:		
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at March 31, 2024 and December 31, 2023; issued and outstanding shares - 0 at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.01 par value: Authorized shares - 75,000,000 at March 31, 2024 and December 31, 2023; issued 8,132,007 and 8,125,728 at March 31, 2024 and December 31, 2023, respectively and outstanding shares - 8,107,121 and 8,102,555 at March 31, 2024 and December 31, 2023, respectively	81	81
Treasury stock, at cost, 24,886 and 23,173 shares at March 31, 2024 and December 31, 2023, respectively	(201)	(196)
Additional paid-in capital	189,517	188,937
Accumulated deficit	(171,958)	(161,517)
Total stockholders' equity	17,439	27,305
Total liabilities and stockholders' equity	$ 28,078	$ 40,638

Source: Lumos Pharma, Inc.