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

Mar 7, 2024

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, Texas, March 07, 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
  - 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 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 ~$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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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,	
	2023	**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

Source: Lumos Pharma, Inc.