Lumos Pharma Reports First Quarter 2023 Financial Results, Provides Clinical Updates

May 3, 2023

-- Patient Enrollment Completed in both Phase 2 OraGrowtH Trials --
-- Primary Outcome Data for both OraGrowtH Trials Expected 4Q 2023 --
-- Interim Data from OraGrowtH Trials Accepted for Presentation at PES 2023 –
-- Conference Call Scheduled for Today at 4:30pm ET --

AUSTIN, Texas, May 03, 2023 (GLOBE NEWSWIRE) -- Lumos Pharma, Inc. (NASDAQ:LUMO), a biopharmaceutical company advancing an oral therapeutic candidate for Pediatric Growth Hormone Deficiency (PGHD) through Phase 2 clinical trials, today announced financial results for the quarter ended March 31, 2023.

"With both our Phase 2 OraGrowtH210 and OraGrowtH212 Trials evaluating oral LUM-201 in moderate (idiopathic) PGHD fully enrolled, we look forward to announcing top line results in the fourth quarter of 2023," said Rick Hawkins, Chair and CEO of Lumos Pharma. "We were also pleased to see updated interim data from these two OraGrowtH Trials highlighted at the *2023 IMPE* meeting and accepted for presentation at the upcoming *2023 PES* annual meeting. These data reinforce our prediction from our interim analysis that the 1.6 mg/kg dose is on track to meet growth expectations in moderate PGHD patients based on historical database averages. The presented data further demonstrate that LUM-201 possesses both a favorable safety profile and a natural, endogenous mechanism of action with potency to stimulate meaningful growth in this idiopathic PGHD patient population."

Recent Highlights

- Interim Data from OraGrowtH210 and OraGrowtH212 Trials accepted for presentation at annual *Pediatric Endocrine Society (PES)* Meeting (May 5-8)
  - An oral presentation on OraGrowtH210 Trial interim data will be given by Andrew Dauber, MD, Chief of Endocrinology, Children's National Hospital
  - A poster presentation on OraGrowtH212 Trial interim data by Fernando Cassorla, MD, Chief of Pediatric Endocrinology, University of Chile, will be presented by David B. Karpf, MD, Chief Medical Officer, Lumos Pharma

- Additional OraGrowtH212 Trial data and interim OraGrowtH210 Trial data were presented at the 2023 *International Meeting of Pediatric Endocrinology (IMPE)* (Mar 4-7)

  - An oral presentation by Fernando Cassorla, MD, on OraGrowtH212 data further supported the pulsatile MOA of LUM-201 and highlighted growth stimulated by oral LUM-201 in PEM-positive PGHD subjects
  - OraGrowtH210 interim data were presented in a poster by Alison Lunsford, MD, Assistant Professor, Texas Tech Physicians of Amarillo, demonstrating the favorable safety and tolerability profile of LUM-201 and that the 1.6 mg/kg/day LUM-201 dose demonstrated 8.6 cm/yr 6-month annualized height velocity in line with historical growth for moderate idiopathic PGHD patients treated with injectable standard of care (rhGH)

- OraGrowtH210 and OraGrowtH212 Trials are fully enrolled as announced on February 28, 2023

  - Between interim and full enrollment, age and other baseline characteristics for OraGrowtH210 subjects converged across 1.6mg LUM-201 and rhGH cohorts as predicted given the stratification of the trial by age and the balancing effect of the additional subjects included at full enrollment

- Primary outcome data from OraGrowtH210 and OraGrowtH212 Trials are expected Q4 2023

Financial Results for the Quarter Ended March 31, 2023

Cash Position – Lumos Pharma ended the quarter on March 31, 2023 with cash, cash equivalents and short-term investments totaling $58.0 million compared to $67.4 million on December 31, 2022. The Company expects an average cash use of approximately $9.5 to $10.5 million per quarter through 2023. Cash on hand as of March 31, 2023 is expected to support operations into the third quarter of 2024, well beyond top line results from our Phase 2 OraGrowtH210 and OraGrowtH212 Trials expected in the fourth quarter of 2023.

R&D Expenses – Research and development expenses for the quarter ended March 31, 2023 were $4.4 million, an increase of approximately $0.1 million compared to the same period in 2022.

G&A Expenses – General and administrative expenses for the quarter ended March 31, 2023 were $4.4 million, an increase of approximately $0.7 million over the same period in 2022, primarily due to increases of $0.4 million in licensing expenses, $0.1 million in personnel-related expenses and $0.2 million in travel expenses.

Net Loss – The net loss for the quarter ended March 31, 2023 was $7.3 million compared to a net loss of $7.7 million for the same period in 2022.

Lumos Pharma had 8,183,296 shares outstanding as of March 31, 2023.

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 into 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's Clinical Trials

Phase 2 OraGrowtH210 Trial of Oral LUM-201 in PGHD

The OraGrowtH210 Trial is a multi-site, global trial evaluating orally administered LUM-201 at three dose levels (0.8, 1.6, 3.2 mg/kg/day) against a standard 0.34 mcg/kg/day dose of injectable rhGH in 82 subjects diagnosed with idiopathic (moderate) PGHD, all of whom are also Predictive Enrichment Marker (PEM) positive. The objective of this trial is to identify the optimal dose of LUM-201 to be used in a Phase 3 registration trial, based on annualized height velocity from a 6-month dataset with durability data of up to 24 months, and to prospectively confirm the utility of our PEM strategy. The complete set of 6-month, primary outcome data for up to 82 subjects is anticipated in the fourth quarter of 2023.

OraGrowtH212 Trial Evaluating PK/PD and Pulsatility of Oral LUM-201 in PGHD

The OraGrowtH212 Trial is a single site, open-label trial evaluating the pharmacokinetic (PK) and pharmacodynamic (PD) effects of oral LUM-201 in 22 PGHD subjects at two dose levels, 1.6 and 3.2 mg/kg/day. The primary objective of the OraGrowtH212 Trial is to confirm prior clinical data demonstrating that the restoration of natural pulsatile release of endogenous growth hormone from LUM-201 therapy, contributes to its efficacy in PGHD. The primary endpoint for this trial is 6 months of PK/PD (pulsatility) and height velocity data in the randomized subjects. Subjects will be allowed to remain on treatment until they reach a bone age of 14 for females and 16 for males reflecting near-adult height. Primary data readout is anticipated in the fourth quarter of 2023.

Switch Study, OraGrowtH213 Trial, Evaluating LUM-201 in OraGrowtH210 Subjects Previously on rhGH

The OraGrowtH213 Trial is 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 patients who have completed the OraGrowtH210 Trial. Subjects will be administered LUM-201 at a dose level of 3.2 mg/kg/day for up to 12 months.

Lumos Pharma Collaboration with Massachusetts General Hospital Evaluating LUM-201 in NAFLD

Lumos Pharma has entered a collaboration with Massachusetts General Hospital (MGH) to evaluate LUM-201 in patients with nonalcoholic fatty liver disease (NAFLD). GH is a critical stimulator of lipolysis, and shows anti-inflammatory effects, and preclinical data suggest that amplifying GH secretion has the potential to reduce hepatic steatosis and prevent NAFLD progression. Interestingly, 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. This MGH investigator-initiated trial is a single-site, 6-month, open-label pilot study of daily oral LUM-201 in adults with NAFLD. The trial will evaluate a dose of 25 mg/day of LUM-201 in 10 subjects with NAFLD and relative IGF-1 deficiency. The primary endpoints will be to determine the reduction in liver lipid content and inflammation, and impact on fibrosis in these subjects administered oral LUM-201 compared to each subject's baseline.

About Lumos Pharma

Lumos Pharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of therapeutics for rare diseases. Lumos Pharma was founded and is led by a management team with longstanding experience in rare disease drug development. Lumos Pharma's lead therapeutic candidate is LUM-201, an oral growth hormone stimulating small molecule, currently being evaluated in several Phase 2 clinical trials for the treatment of Pediatric Growth Hormone Deficiency (PGHD): the dose-finding OraGrowtH210 Trial; a PK/PD mechanistic trial, the OraGrowtH212 Trial; and a switch trial, the OraGrowtH213 Trial. If approved by the FDA, LUM-201 would provide an orally administered alternative to recombinant growth hormone injections that PGHD subjects otherwise endure for many years of treatment. LUM-201 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 therapeutics that are safe, efficacious, and offer a 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 encouraging growth response in our LUM-201 trials, progress in our clinical efforts including the timing of expected results on our trials and our ability to continue advancing our trials, 1.6 mg/kg/day as the optimal dose for our Pivotal Phase 3 trial, plans related to initiation and execution of clinical

trials; our prediction from our interim analysis that the 1.6 mg/kg dose is on track to meet growth expectations in moderate PGHD patients based on historical database averages, that the presented data further demonstrate that LUM-201 possesses both a favorable safety profile and a natural, endogenous mechanism of action with potency to stimulate meaningful growth in this idiopathic PGHD patient population, plans related to moving additional indications into clinical development; future financial performance, results of operations, our expected average cash use per quarter through 2023 and that cash on hand as of March 31, 2023 is expected to support operations into 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 final results of our LUM-201 Trials being different than our interim results, the effects of pandemics, other widespread health problems or military conflicts including the Ukraine-Russia conflict, the outcome of our future interactions with regulatory authorities, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to obtain and maintain the necessary patient enrollment for our product candidate in a timely manner, the ability to successfully develop our product candidate, the timing and ability of Lumos to raise additional equity capital as needed 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, 2022, 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,	
	2023	**2022**
Revenues:		
Royalty revenue	$ 691	$ 111
Total revenues	691	111
Operating expenses:		
Research and development	4,369	4,221
General and administrative	4,357	3,621
Total operating expenses	8,726	7,842
Loss from operations	(8,035)	(7,731)
Other income and expense:		
Other income, net	119	6
Interest income	570	5
Other income, net	689	11
Net loss	$ (7,346)	$ (7,720)
Net loss per share:		
Basic and diluted	$ (0.89)	$ (0.92)
Weighted average number of common shares outstanding:		
Basic and diluted	8,239,941	8,357,969
Other comprehensive income:		
Unrealized gain on short-term investments	4	—
Total comprehensive loss	$ (7,342)	$ (7,720)

Lumos Pharma, Inc.
Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	March 31, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 44,038	$ 56,007
Short-term investments	13,945	11,352
Prepaid expenses and other current assets	5,070	4,427
Income tax receivable	200	223
Total current assets	63,253	72,009
Non-current assets:		
Property and equipment, net	52	53
Right-of-use asset	420	230
Total non-current assets	472	283
Total assets	$ 63,725	$ 72,292
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 837	$ 275
Accrued expenses	3,948	6,200
Current portion of lease liability	232	233
Total current liabilities	5,017	6,708
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	189	—
Total long-term liabilities	6,189	6,000
Total liabilities	$ 11,206	$ 12,708
Commitments and contingencies:		
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at March 31, 2023 and December 31, 2022; issued and outstanding shares - 0 at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.01 par value: Authorized shares - 75,000,000 at March 31, 2023 and December 31, 2022; issued 8,200,043 and 8,283,708 at March 31, 2023 and December 31, 2022, respectively and outstanding shares - 8,183,296 and 8,267,968 at March 31, 2023 and December 31, 2022, respectively	81	82
Treasury stock, at cost, 16,747 and 15,740 shares at March 31, 2023 and December 31, 2022, respectively	(174)	(170)
Additional paid-in capital	187,446	187,164
Accumulated deficit	(134,829)	(127,483)
Accumulated other comprehensive loss	(5)	(9)
Total stockholders' equity	$ 52,519	$ 59,584
Total liabilities and stockholders' equity	$ 63,725	$ 72,292

Source: Lumos Pharma, Inc.