Lumos Pharma Reports Second Quarter 2023 Financial Results, Provides Clinical Update

Aug 9, 2023

- *Confirms Timing for Primary Outcome Data Readout for two Phase 2 OraGrowtH Trials in Q4 2023*
- *Late Breaking Abstract Accepted for Oral Presentation at ESPE 2023*
- *Encouraging Interim Data from OraGrowtH Trials Presented at ENDO 2023, Highlighted in KOL Webinar*
- *Conference Call Scheduled for Today at 4:30pm ET*

AUSTIN, Texas, Aug. 09, 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 second quarter ended June 30, 2023.

"We are pleased to confirm our expectation for primary data readout from our two Phase 2 OraGrowtH Trials evaluating LUM-201 in idiopathic PGHD in the fourth quarter of 2023," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "The primary endpoint for these trials is annualized height velocity at six months on treatment with LUM-201. Given the encouraging data and new analysis presented at ENDO and highlighted in the Key Opinion Leader (KOL) webinar we hosted in June, our convictions are further reinforced that at least one of the LUM-201 dose cohorts will meet growth expectations based on historical averages, and that the LUM-201 mechanism of action and potency can elicit sustained improvements in growth in the moderate PGHD patient population. We look forward to additional analysis of LUM-201 data to be presented at the upcoming ESPE conference in September, and to continuing to advance our LUM-201 clinical program for potentially the first oral therapeutic for PGHD."

Recent Highlights

- **Company reiterates Q4 2023 timing for primary outcome data readout of OraGrowtH210 & OraGrowtH212 Trials**
  - Primary endpoint is annualized height velocity (AHV) at 6 months on treatment with the prediction of growth of 8.3 to 8.6 cm/yr based on historical data for this moderate idiopathic PGHD population
  - Other objectives of the OraGrowtH210 Trial are to confirm the utility of the predictive enrichment marker (PEM) strategy and determine the optimal dose for a Phase 3 trial
  - Up to 82 subjects (approximately 20 per cohort) were enrolled in the OraGrowtH210 Trial
  - Up to 22 subjects (approximately 11 per cohort) were enrolled in the OraGrowtH212 Trial
  - AHV data at 12 months on treatment is expected for up to 12 subjects per OraGrowtH210 cohort and up to 7 subjects per OraGrowtH212 cohort, for a total of up to 62 subjects from both trials
  - Additional AHV data at 18 and 24 months on treatment are also expected for a small number of subjects
  - As with all Phase 2 trials in PGHD, OraGrowtH210 is *not* powered to show non-inferiority of AHV between LUM-201 and the control; these Phase 2 data will support the safety profile and the selection of a LUM-201 dose for Phase 3 wherein non-inferiority to a control rhGH arm of < 2 cm should determine success based on historical approvals
- **Data abstract accepted for oral presentation at upcoming European Society of Pediatric Endocrinology (ESPE) annual meeting, September 21-23, 2023, in The Hague, Netherlands**
  - Late-breaking abstract—*Deconvolution Analysis: GH secretagogue (LUM-201) enhances growth in individuals with moderate idiopathic Pediatric Growth Hormone Deficiency (iPGHD) by enhancing endogenous GH secretion and increasing IGF-1*, (Fernando Cassorla, MD)—accepted for oral presentationSaturday, September 23 (9:30-10:30 AM CET)
- **Positive results from Massachusetts General Hospital (MGH) study of injectable growth hormone in NAFLD published in Journal of Clinical Endocrinology and Metabolism – Data support MGH pilot trial evaluating oral LUM-201 in same indication**
  - *Growth Hormone Administration Improves Nonalcoholic Fatty Liver Disease in Overweight/Obesity: A Randomized Trial* —Dichtel, et al.
    - Investigators hypothesized that growth hormone may reduce hepatic steatosis in obese subjects with NAFLD
    - Subjects were randomly assigned to a treatment group (27 GH; 26 placebo), with 41 completers (20 GH and 21 placebo) at 6 months.
    - Reduction in absolute % Intrahepatic Lipid (IHL) content by proton magnetic resonance spectroscopy was significantly greater in the GH vs placebo cohorts
  - Investigators concluded that GH reduces liver fat without commensurate weight loss; data support evaluation of oral LUM-201 in the same indication (NAFLD)
  - The LUM-201 pilot trial in NAFLD continues to enroll; the Company's primary near-term focus remains on

advancing LUM-201 in PGHD

- **New LUM-201 data and analysis presented at ENDO 2023, highlighted in KOL webinar**
  - Data from two oral presentations presented at ENDO were highlighted by two distinguished KOLs in a webinar held on June 21, 2023. Details included:
  - New data from the OraGrowthH212 Trial showed an increase in IGF-1 levels on LUM-201 at 6 months that remained within normal range, an increase in IGF-1 SDS to > 0, and a durable growth response after 12 months of LUM-201 administration; clear evidence of potential drug effect for LUM-201 was also observed in consistent improvement in AHV over baseline
  - New analysis of combined OraGrowthH210 and OraGrowthH212 trial data at the 1.6 mg/kg/day and 3.2mg/kg/day dose levels (15 subjects from OraGrowthH212, 20 subjects from OraGrowthH210): results continue to demonstrate that there is a durable response to LUM-201 from 6 to 12 months
  - A replay of the webinar is here and the presented slides are available here

Financial Results for the Quarter Ended June 30, 2023

Cash Position – Lumos Pharma ended the quarter on June 30, 2023 with cash, cash equivalents and short-term investments totaling $50.9 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 June 30, 2023 is expected to support operations for at least 12 months following the date of the filing of our second quarter 2023 financial statements.

R&D Expenses – Research and development expenses increased by $1.4 million for the three months ended June 30, 2023 compared to the same period in 2022 primarily due to increases of $1.1 million in contract manufacturing expenses, $0.4 million in clinical trial expenses and $0.1 million in personnel-related expenses, offset by a $0.2 million decrease in consulting expenses.

G&A Expenses – General and administrative expenses increased by $0.5 million for the three months ended June 30, 2023 compared to the same period in 2022 primarily due to increases of $0.2 million in personnel-related expenses, $0.1 million in stock compensation expenses, $0.1 million in travel expenses and $0.1 million in royalty expenses.

Net Loss – The net loss for the quarter ended June 30, 2023 was $8.9 million compared to a net loss of $7.8 million for the same period in 2022.

Lumos Pharma ended Q2 2023 with 8,041,345 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 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 OraGrowthH210 Trial of Oral LUM-201 in PGHD

The OraGrowthH210 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 dose of injectable rhGH in approximately 80 subjects diagnosed with idiopathic (moderate) PGHD, which is less severe than organic PGHD. 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, and to prospectively confirm the preliminary validation of our Predictive Enrichment Marker (PEM) strategy. The complete set of 6-month, primary outcome data for 82 subjects is anticipated in the fourth quarter of 2023. Subjects will be dosed for a total of 24 months.

OraGrowthH212 Trial Evaluating PK/PD and Pulsatility of Oral LUM-201 in PGHD

The OraGrowthH212 Trial is a single site, open-label trial evaluating the pharmacokinetic (PK) and pharmacodynamic (PD) effects of oral LUM-201 in up to 24 PGHD subjects at two dose levels, 1.6 and 3.2 mg/kg/day. The primary objective of the OraGrowthH212 Trial is to confirm prior clinical data demonstrating the amplified 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 in 22 subjects is anticipated in the fourth quarter of 2023.

Switch Study, OraGrowthH213 Trial, Evaluating LUM-201 in OraGrowthH210 Subjects Previously on rhGH

The OraGrowthH213 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 OraGrowthH210 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, inflammation, and fibrosis in these subjects administered 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. 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 $4.5B 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 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, progress in our clinical efforts including the timing of expected results on our LUM-201 trials and our ability to continue advancing our trials, encouraging interim data and new analysis presented, that our convictions are further reinforced that at least one of the LUM-201 dose cohorts will meet growth expectations based on historical averages, that the LUM-201 mechanism of action and potency can elicit sustained improvements in growth in the moderate PGHD patient population, looking forward to additional analysis of LUM-201 data to be presented at the upcoming ESPE conference, continuing to advance our LUM-201 clinical program for potentially the first oral therapeutic for PGHD, that growth hormone may reduce hepatic steatosis in obese subjects with NAFLD, future financial performance, results of operations, our expected average cash use per quarter through 2023 and that cash on hand as of June 30, 2023 is expected to support operations for the next 12 months 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 outcome of our future interactions with regulatory authorities, the timing and ability of Lumos to raise additional equity capital as needed to fund our Phase 3 Trial or for other purposes, 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 effects of pandemics, other widespread health problems or military conflicts including the Ukraine-Russia 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 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Royalty revenue	$ 527	$ 403	$ 1,218	$ 514
Total revenues	527	403	1,218	514
Operating expenses:				
Research and development	6,024	4,645	10,393	8,866
General and administrative	4,146	3,682	8,503	7,303

Total operating expenses	10,170	8,327	18,896	16,169
Loss from operations	(9,643)	(7,924)	(17,678)	(15,655)
Other income and expense:				
Other income, net	124	6	243	12
Interest income	559	74	1,129	79
Other income, net	683	80	1,372	91
Net loss before taxes	(8,960)	(7,844)	(16,306)	(15,564)
Income tax benefit	29	—	29	—
Net loss	$ (8,931)	$ (7,844)	$ (16,277)	$ (15,564)
Net loss per share:				
Basic and diluted	$ (1.09)	$ (0.94)	$ (1.98)	$ (1.86)
Weighted average number of common shares outstanding:				
Basic and diluted	8,164,603	8,366,445	8,205,625	8,361,907
Other comprehensive loss:				
Unrealized loss on short-term investments	(6)	—	(2)	—
Total comprehensive loss	$ (8,937)	$ (7,844)	$ (16,279)	$ (15,564)

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

	June 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 37,862	$ 56,007
Short-term investments	12,989	11,352
Prepaid expenses and other current assets	4,899	4,427
Other receivables	233	223
Total current assets	55,983	72,009
Non-current assets:		
Property and equipment, net	45	53
Right-of-use asset	345	230
Total assets	$ 56,373	$ 72,292
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 279	$ 275
Accrued expenses	6,087	6,200
Current portion of lease liability	179	233
Total current liabilities	6,545	6,708
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	167	—
Total liabilities	12,712	12,708
Commitments and contingencies:		
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at June 30, 2023 and December 31, 2022; issued and outstanding shares - 0 at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.01 par value: Authorized shares - 75,000,000 at June 30, 2023 and December 31, 2022; issued 8,061,920 and 8,283,708 at June 30, 2023 and December 31, 2022, respectively and outstanding shares - 8,041,345 and 8,267,968 at June 30, 2023 and December 31, 2022, respectively	80	82
Treasury stock, at cost, 20,575 and 15,740 shares at June 30, 2023 and December 31, 2022, respectively	(187)	(170)
Additional paid-in capital	187,539	187,164
Accumulated deficit	(143,760)	(127,483)
Accumulated other comprehensive loss	(11)	(9)
Total stockholders' equity	43,661	59,584
Total liabilities and stockholders' equity	$ 56,373	$ 72,292

Source: Lumos Pharma, Inc.