



Lumos Pharma Reports Full Year 2022 Financial Results, Provides Clinical Development Updates

March 1, 2023

-- Patient Enrollment Completed in OraGrowthH210 and OraGrowthH212 Trials --

-- Primary Outcome Data for both OraGrowthH Trials Expected Q4 2023 --

-- Additional Data from OraGrowthH Trials to be Presented at IMPE 2023 --

-- Conference Call Scheduled for Today at 4:30 ET --

AUSTIN, Texas, March 01, 2023 (GLOBE NEWSWIRE) -- [Lumos Pharma, Inc.](#) (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, today announced financial results for the year ended December 31, 2022.

"We are pleased with the progress we made in 2022 advancing two Phase 2 OraGrowthH Trials evaluating our oral therapeutic candidate, LUM-201, in idiopathic PGHD," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "Furthermore, with both the OraGrowthH210 and OraGrowthH212 Trials now fully enrolled, we look forward to completing these trials and announcing top line results in the fourth quarter of 2023. We continue to advance our LUM-201 clinical program and plan for our pivotal Phase 3 trial for potentially the first oral therapeutic for PGHD."

Recent Highlights

- **Patient Enrollment Completed in Two Phase 2 OraGrowthH Trials Evaluating Oral LUM-201 in Idiopathic (moderate) PGHD.** The last subjects have been randomized in our OraGrowthH210 and OraGrowthH212 Trials, and we now expect primary outcome data on 82 subjects in the OraGrowthH210 Trial and 22 subjects in the PK/PD OraGrowthH212 Trial in the fourth quarter of 2023.
- **Interim analyses for Phase 2 OraGrowthH210 and PK/PD OraGrowthH212 Trials announced November 2022.** Data from the interim analysis of our OraGrowthH210 Trial showed LUM-201 met growth expectations, showed durable response and was well-tolerated. Data support the selection of 1.6 mg/kg/day as the optimal dose for our pivotal Phase 3 trial. The control arm for this interim analysis included outliers with growth greater than prior data precedents, the impact of which we expect to diminish with full enrollment. Interim data from our OraGrowthH212 Trial were supportive of the OraGrowthH210 Trial data.
- **Key Opinion Leaders encouraged by interim OraGrowthH Trials data.** We hosted a webinar featuring Drs. Andrew Dauber and Fernando Cassorla, distinguished opinion leaders in the field of pediatric endocrinology, for a discussion of the interim data from our Phase 2 OraGrowthH210 and PK/PD OraGrowthH212 Trials. A replay of the event is available in the "[Events & Presentations](#)" section under "Investors & Media" on our website.
- **Pilot Investigator-Initiated Trial evaluating LUM-201 in NAFLD supported by prior data.** As previously announced, we entered into a clinical collaboration with Dr. Laura Dichtel and Massachusetts General Hospital to explore the potential of LUM-201 in Nonalcoholic Fatty Liver Disease (NAFLD) in an investigator sponsored pilot study. Encouraging data presented by Dr. Dichtel at ENDO 2022 ([abstract](#)) evaluating injectable growth hormone in NAFLD supported the assessment of oral LUM-201 in the same indication. Enrollment in the trial is ongoing.
- **Additional Data on LUM-201 OraGrowthH Trials to be presented in an oral and a poster presentation at the 2023 International Meeting of Pediatric Endocrinology (IMPE) in Buenos Aires, Argentina March 4-7, 2023.** We are pleased to have two abstracts accepted for presentation at the upcoming IMPE meeting. Details are as follows:
 - Oral Presentation - *Dose-dependent Increase in GH AUC_{0-12h} with LUM-201 in Idiopathic Pediatric GH Deficiency (iPGHD) from the Interim Analysis Data of the OraGrowthH212 Trial*
 - Poster Presentation - *Baseline Demographics of the OraGrowthH210 Trial Studying LUM-201 in Idiopathic Pediatric Growth Hormone Deficiency (iPGHD) Interim Analysis Data*
- **Formulation patent for LUM-201 filed November 2022.** In November 2022, we filed a patent application PCT/US22/050700 titled "Compactable Oral Formulations of lbutamoren." The application is currently pending and contains claims directed to certain improved formulations we intend to utilize in our Phase 3 trial and ultimately commercialize. If granted, this patent would provide composition of matter protection through November 2042 for the commercialized version of

LUM-201.

Financial Results for the Year Ended December 31, 2022

- **Cash Position** – Lumos Pharma ended the year on December 31, 2022, with cash, cash equivalents, and short-term investments totaling \$67.4 million compared to \$94.8 million on December 31, 2021. The Company expects an average cash use of approximately \$9.5 to \$10.5 million per quarter through 2023. Cash on hand as of December 31, 2022 is expected to support operations into the third quarter of 2024.
- **R&D Expenses** – Research and development expenses were \$17.9 million, an increase of \$1.6 million for the year ended December 31, 2022 compared to the same period in 2021, primarily due to increases of \$1.1 million in clinical trial and contract manufacturing expenses, \$0.5 million in consulting expenses and \$0.3 million in personnel-related expenses, offset by decreases of \$0.2 million in stock compensation expenses and \$0.1 million in operating expenses for supplies, depreciation and rent.
- **G&A Expenses** – General and administrative expenses were \$15.7 million, an increase of \$0.4 million for the year ended December 31, 2022 compared to the same period in 2021, primarily due to increases of \$0.9 million in royalty expenses, \$0.4 million in travel expense and \$0.3 million in other expenses, offset by decreases of \$0.4 million in personnel-related expenses, \$0.4 million in stock compensation expenses, \$0.3 million in consulting expenses and \$0.1 million in operating expenses for supplies, depreciation and rent.
- **Net Loss** – The net loss for the year ended December 31, 2022, was \$31.1 million compared to a net loss of \$30.4 million for the same period in 2021.
- Lumos Pharma ended Q4 2022 with 8,267,968 shares outstanding.

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.

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. 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 a Phase 2 clinical trial, the OraGrowth210 Trial, and a PK/PD trial, the OraGrowth212 Trial, for the treatment of Pediatric Growth Hormone Deficiency (PGHD). If approved by the FDA, LUM-201 would provide an orally administered alternative to recombinant growth hormone injections that PGHD patients 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 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, that the control arm for this interim analysis included outliers with growth greater than prior data precedents and that the impact of which we expect to diminish with full enrollment, encouraging data presented by Dr. Dichtel, that we intend to use our formulation patent in our Phase 3 trial, market reception to our treatment regimen for PGHD and other indications, plans related to initiation and execution of clinical trials; 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 December 31, 2022 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, 2021, 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, 2022. 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,	
	2022	2021
Revenues:		
Licensing and collaboration revenue	\$ —	\$ 10
Royalty revenue	1,523	220
Total revenues	<u>1,523</u>	<u>230</u>
Operating expenses:		
Research and development	17,857	16,246
General and administrative	15,706	15,331
Total operating expenses	<u>33,563</u>	<u>31,577</u>
Loss from operations	(32,040)	(31,347)
Other income and expense:		
Other income, net	91	269

Interest income	874	12
Other income, net	965	281
Net loss before taxes	(31,075)	(31,066)
Income tax benefit	13	636
Net loss	(31,062)	(30,430)
Net loss per share of common stock Basic and diluted	\$ (3.71)	\$ (3.65)
Weighted average number of common shares outstanding Basic and diluted	8,373,821	8,334,516
Other comprehensive loss		
Unrealized loss on short-term investments	\$ (9)	\$ —
Total comprehensive loss	\$ (31,071)	\$ (30,430)

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

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 56,007	\$ 94,809
Short-term investments	11,352	—
Prepaid expenses and other current assets	4,427	4,740
Other receivables	223	128
Total current assets	72,009	99,677
Non-current assets:		
Property and equipment, net	53	79
Right-of-use asset	230	556
Total non-current assets	283	635
Total assets	\$ 72,292	\$ 100,312
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 275	\$ 612
Accrued expenses	6,200	4,166
Current portion of lease liability	233	352
Total current liabilities	6,708	5,130
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	—	205
Total long-term liabilities	6,000	6,205
Total liabilities	12,708	11,335
Commitments and contingencies:		
Stockholders' equity:		
Undesignated preferred stock, \$0.01 par value: Authorized shares - 5,000,000 at December 31, 2022 and 2021; issued and outstanding shares - 0 at December 31, 2022 and 2021	—	—
Common stock, \$0.01 par value: Authorized shares - 75,000,000 at December 31, 2022 and 2021; issued shares - 8,283,708 and 8,366,819 at December 31, 2022 and 2021, respectively, and outstanding shares - 8,267,968 and 8,357,391 at December 31, 2022 and 2021, respectively	82	83
Treasury stock, at cost, 15,740 and 9,428 shares held as of December 31, 2022 and 2021, respectively	(170)	(114)
Additional paid-in capital	187,164	185,429
Accumulated deficit	(127,483)	(96,421)
Accumulated other comprehensive loss	(9)	—
Total stockholders' equity	59,584	88,977
Total liabilities and stockholders' equity	\$ 72,292	\$ 100,312



Source: Lumos Pharma, Inc.