



Lumos Pharma Reports First Quarter 2022 Financial Results and Clinical Development Updates

May 10, 2022

--Phase 2 OraGrowthH210 Trial Reached 50% Randomization Milestone – Interim Data from Phase 2 and PK/PD OraGrowth Trials Anticipated by End of 2022--

--FDA Permits Treatment with LUM-201 Beyond 12 Months and Lifts Partial Clinical Hold--

--Clinical Collaboration Initiated with Massachusetts General Hospital for Evaluation of LUM-201 in Nonalcoholic Fatty Liver Disease (NAFLD) in Phase 2 Pilot Trial--

AUSTIN, Texas, May 10, 2022 (GLOBE NEWSWIRE) -- [Lumos Pharma, Inc.](#) (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, today announced financial results for the quarter ended March 31, 2022 and clinical development updates.

"To date, 2022 has been a productive period for Lumos, with encouraging enrollment trends in both of our OraGrowthH210 and OraGrowthH212 trials evaluating orally administered LUM-201 in pediatric growth hormone disease (PGHD) and our announcement of planned interim data analyses by the end of this year," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "Other notable events included a journal publication of a peer-reviewed article supporting LUM-201 as a potent GH secretagogue, and the removal of partial clinical hold for treatment past 12 months. With momentum building in our LUM-201 program for PGHD, we are also honored to collaborate with Mass General on an investigator-initiated trial evaluating LUM-201 in NAFLD. We continue to execute on our clinical programs and look forward to interim data from our OraGrowth Trials later this year."

Recent Highlights

- **Phase 2 OraGrowthH210 Trial exceeds 50% randomization – Interim analyses for OraGrowthH210 and PK/PD OraGrowthH212 Trials by end of 2022.** OraGrowthH210 has now exceeded the 50% randomization milestone, and subject enrollment in both the OraGrowthH210 and OraGrowthH212 Trials is progressing sufficiently for us to confirm our plan to conduct interim analyses of data from both trials by the end of 2022. We believe the interim data should provide an early indication of efficacy and safety of oral LUM-201 versus standard of care daily rhGH injections in PGHD. We continue to anticipate primary outcome data on 80 subjects from our OraGrowthH210 Trial in the second half of 2023.
- **FDA lifts partial clinical hold on treatment beyond 12 months after review of preliminary data from OraGrowth trials.** In July 2021, we announced that the U.S. Food & Drug Administration (FDA) had restricted treatment with LUM-201 to no more than 12 months. Based on a review of preliminary safety and efficacy data from both OraGrowth trials in progress the FDA has lifted the partial hold and will now permit treatment with LUM-201 beyond twelve months. As a result, the OraGrowthH210 Trial will be extended to 24 months to allow subjects to continue LUM-201 therapy uninterrupted. Additionally, we plan to extend the duration of the OraGrowthH212 Trial.
- **Peer-reviewed journal publication demonstrates LUM-201's potency as GH secretagogue.** A peer-reviewed article illustrating LUM-201's greater potency over standard growth hormone secretagogues was published March 30, 2022, in the journal, [Hormone Research in Paediatrics](#). The article, co-authored by George Bright, MD and Michael Thorner, MB, BS, entitled "A GH Secretagogue Receptor Agonist (LUM-201) Elicits Greater GH Responses than Standard GH Secretagogues in Subjects of a Pediatric GH Deficiency Trial," further supports prior data suggesting LUM-201's therapeutic potential when administered to pediatric subjects with idiopathic growth hormone deficiency.
- **Lumos Pharma collaborates with Massachusetts General to evaluate LUM-201 in NAFLD.** The Company 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-initiated pilot study. While we remain focused on our core LUM-201 program in PGHD, the Company is pleased to support Mass General's exploration of LUM-201's potential in this indication, a condition estimated to be prevalent in approximately 25% of adults worldwide. NAFLD can often advance to the more serious liver disease non-alcoholic steatohepatitis (NASH) with fibrosis, and NASH-associated liver failure is one of the leading causes of liver transplants in the United States.

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 interim analysis will evaluate the safety and annualized height velocity of the three dose levels of LUM-201 against a standard dose of injectable recombinant human growth hormone (rhGH) in a minimum of 40 subjects at six months on therapy. The complete set of 6-month, primary outcome data for 80 patients is anticipated in the second half 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 objective of the OraGrowthH212 Trial is to confirm prior clinical data demonstrating the amplified pulsatile release of endogenous growth hormone from LUM-201 therapy differentially contributes to its efficacy in PGHD. The primary endpoint for this trial is six months of PK/PD and height velocity data in up to 24 subjects. Subjects will be dosed for a total of 12 months, with a plan to extend the duration of the trial. Interim data on a minimum of 10 subjects is anticipated by the end of 2022.

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 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 potentially fibrosis in these subjects administered LUM-201 compared to historical placebo-treated controls.

Financial Results for the Quarter Ended March 31, 2022

- Cash Position – Lumos Pharma ended the quarter on March 31, 2022 with cash and cash equivalents totaling \$86.8 million compared to \$94.8 million on December 31, 2021. The Company expects an average cash use of approximately \$8.5 to \$9.5 million per quarter through 2022. Cash on hand as of March 31, 2022 is expected to support operations through the primary outcome data readout from the OraGrowthH210 Trial anticipated in the second half of 2023 and the OraGrowthH212 Trial.
- R&D Expenses – Research and development expenses were \$4.2 million for the quarter ended March 31, 2022, a decrease compared to \$4.7 million for the same period in 2021, primarily due to decreases of \$0.5 million in personnel-related expenses, \$0.3 million in stock compensation expenses and \$0.1 million in legal and consulting expenses, offset by an increase of \$0.5 million in clinical trial and contract manufacturing expenses.
- G&A Expenses – General and administrative expenses were \$3.6 million for the quarter ended March 31, 2022, a decrease compared to \$4.0 million for the same period in 2021, primarily due to decreases of \$0.3 million in legal and consulting expenses, \$0.2 million in stock compensation expenses, and \$0.1 million in depreciation expenses, offset by increases of \$0.1 million in licensing expenses and \$0.2 million in other expenses.
- Net Loss – The net loss for the quarter ended March 31, 2022 was \$7.7 million compared to net loss of \$8.6 million for the same period in 2021.
- Lumos Pharma ended the first quarter 2022 with 8,358,625 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.

Access to the live conference call is available five minutes prior to the start of the call by dialing (855) 469-0612 (U.S.) or (484) 756-4268 (international). The conference call will be webcast live and a link to the webcast can be accessed through the Lumos Pharma website at <https://lumos-pharma.com/> in the "Investors & Media" section under "Events and Presentations" or through this link: <https://edge.media-server.com/mmc/p/fz7qwz46>. To ensure a timely connection, it is recommended that users register at least 10 minutes prior to the scheduled webcast. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (international) and using the passcode 9647959. The replay will be available for two weeks from the date of the call.

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 and received early funding from leading healthcare investors, including Deerfield Management, a fund managed by Blackstone Life Sciences, Roche Venture Fund, New Enterprise Associates (NEA), Santé Ventures, and UCB. 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 OraGrowthH210 Trial, a PK/PD trial, the OraGrowthH212 Trial, and a switch trial, the OraGrowthH213 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 progress in our clinical efforts including comments concerning screening and enrollment for our trials, momentum building in our LUM-201 program for PGHD, anticipated timing of interim analyses of trials, our belief that the interim data should provide an early indication of efficacy and safety of oral LUM-201 versus standard of care daily rhGH injections in PGHD, LUM-201's therapeutic potential when administered to pediatric subjects with idiopathic growth hormone deficiency, expecting the primary outcome data readout for our trials, the potential to expand our LUM-201 platform into other indications, anticipated 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, cash position, cash use rate and sufficiency of capital resources to fund our operating requirements through the primary outcome data readout from the OraGrowth210 and OraGrowth212 Trials, 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 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 Quarterly Reports on Form 10-Q. 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
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	2021
Revenues:		
Royalty revenue	111	—
Total revenues	<u>111</u>	<u>—</u>
Operating expenses:		
Research and development	4,221	4,660
General and administrative	3,621	3,957
Total operating expenses	<u>7,842</u>	<u>8,617</u>
Loss from operations	(7,731)	(8,617)
Other income and expense:		
Other income, net	6	20
Interest income	5	3
Interest expense	—	(37)
Other (expense) income, net	<u>11</u>	<u>(14)</u>
Net loss	<u>\$ (7,720)</u>	<u>\$ (8,631)</u>
Net loss per share:		
Basic and diluted	\$ (0.92)	\$ (1.04)
Weighted average number of common shares outstanding:		
Basic and diluted	8,357,969	8,316,888

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 86,758	\$ 94,809
Prepaid expenses and other current assets	5,753	4,740
Income tax receivable	134	128
Total current assets	92,645	99,677
Non-current assets:		
Property and equipment, net	69	79
Right-of-use asset	476	556
Total non-current assets	545	635
Total assets	\$ 93,190	\$ 100,312
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,799	\$ 612
Accrued expenses	3,098	4,166
Current portion of lease liability	345	352
Total current liabilities	5,242	5,130
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	131	205
Total long-term liabilities	6,131	6,205
Total liabilities	11,373	11,335
Commitments and contingencies:		
Stockholders' equity:		
Undesignated preferred stock, \$0.01 par value: Authorized shares - 5,000,000 at March 31, 2022 and December 31, 2021; issued and outstanding shares - 0 at March 31, 2022 and December 31, 2021	\$ —	\$ —
Common stock, \$0.01 par value: Authorized shares - 75,000,000 at March 31, 2022 and December 31, 2021; issued 8,368,521 and 8,366,819 at March 31, 2022 and December 31, 2021, respectively and outstanding shares - 8,358,625 and 8,357,391 at March 31, 2022 and December 31, 2021, respectively	\$ 83	\$ 83
Treasury stock, at cost, 9,896 and 9,428 shares at March 31, 2022 and December 31, 2021, respectively	\$ (119)	\$ (114)
Additional paid-in capital	\$ 185,994	\$ 185,429
Accumulated deficit	\$ (104,141)	\$ (96,421)
Total stockholders' equity	81,817	88,977
Total liabilities and stockholders' equity	\$ 93,190	\$ 100,312



Source: Lumos Pharma, Inc.