# Lumos Pharma Reports Second Quarter 2022 Financial Results and Clinical Development Updates

August 9, 2022

*-- Continue to Anticipate Interim Data from Phase 2 OraGrowtH210 and PK/PD OraGrowtH212 Trials in Q4 2022 --*

*-- Primary Outcome Readouts from Both Trials Anticipated 2H 2023 with Data in up to 24 Patients Anticipated from OraGrowtH212 Trial --*

*-- Cash Runway into Second Quarter 2024 --*

AUSTIN, Texas, Aug. 09, 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 June 30, 2022.

"During our second quarter of 2022 we continued to execute on our clinical programs evaluating orally administered LUM-201 in PGHD and are delighted to reaffirm our commitment to announcing interim data for our OraGrowtH210 and OraGrowtH212 Trials by the end of this year," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "Additionally, we continue to be pleased with our enrollment trends and now expect to release primary outcome data from both OraGrowtH Trials in the second half of 2023. We also continue to support our collaboration with Mass General on an investigator-initiated trial evaluating LUM-201 in NAFLD, which is now prescreening subjects. We look forward to advancing these programs and to the release of interim data from our OraGrowtH Trials later this year."

**Recent Highlights**

- **Interim analyses for Phase 2 OraGrowtH210 and PK/PD OraGrowtH212 Trials by end of 2022**. Both the OraGrowtH210 and OraGrowtH212 Trials in subjects with idiopathic, Predictive Enrichment Marker-(PEM)-positive Pediatric Growth Hormone Deficiency (PGHD) are progressing well, and we confirm our plan to conduct interim analyses in Q4. We believe the interim data should provide an early indication of efficacy and safety of oral LUM-201 versus standard of care daily recombinant human growth hormone (rhGH) injections in idiopathic PGHD. In addition, we are progressing toward full enrollment of both trials, enabling a readout of our primary outcome data on 80 subjects from the OraGrowtH210 Trial in the second half of 2023. The OraGrowtH212 Trial has recently been extended to follow subjects to near adult height. The primary outcome data for this trial on up to 24 subjects is now expected in the second half of 2023, concurrent with the OraGrowtH210 Trial. Our trials are being conducted in the idiopathic subset of the PGHD population, and prior studies demonstrate a slower growth trajectory on rhGH in this subset. Therefore, the appropriate yardstick for growth on LUM-201 in the OraGrowtH210 Trial is the growth on rhGH in the control arm of this trial, not the growth in other trials that typically enroll more severely growth hormone deficient subjects. Baseline characteristics will determine whether we combine the annualized height velocity (AHV) data from both trial datasets at the interim and final analyses.

- **Prescreening continues in Massachusetts General Investigator-Initiated Trial evaluating LUM-201 in NAFLD**. 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. Prescreening in the trial is ongoing, and we expect this trial to begin enrollment in the near future. While we remain focused on our core LUM-201 program in PGHD, we are 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.

**Financial Results for the Quarter Ended June 30, 2022**

- Cash Position – Lumos Pharma ended the quarter on June 30, 2022 with cash and cash equivalents totaling $79.5 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 June 30, 2022 is expected to support operations into the second quarter of 2024, inclusive of the primary outcome data readout from OraGrowtH210 and OraGrowtH212 Trials anticipated in the second half of 2023.
- R&D Expenses – Research and development expenses were $4.6 million for the quarter ended June 30, 2022, an increase compared to $4.1 million for the same period in 2021, primarily due to an increase of $0.3 million in personnel and stock option expense and $0.3 million in legal and consulting expenses, offset by a decrease of $0.1 million in clinical trial and contract manufacturing expenses.
- G&A Expenses – General and administrative expenses were $3.7 million for the quarter ended June 30, 2022, a decrease as compared to $4.6 million for the same period in 2021, primarily due to decreases of $0.6 million in personnel-related expenses, $0.4 million in stock compensation expenses and $0.3 million in legal and other expenses, offset by an increase

of $0.3 million in royalty expenses.

- Net Loss – The net loss for the quarter ended June 30, 2022 was $7.8 million compared to net loss of $8.7 million for the same period in 2021.
- Lumos Pharma ended the second quarter 2022 with 8,377,567 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 (833) 634-2295 (U.S.) or (412) 902-4176 (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/ofen9o6f. 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 (877) 344-7529 (U.S.) or (412) 317-0088 (international) and using the passcode 1602592. The replay will be available for two weeks from the date of the call.

**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 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 (0.24 mg/kg/week, dosed daily) 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.

**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 up to 24 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 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 six months of PK/PD (pulsatility) and height velocity data in up to 24 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 up to 24 patients is anticipated in the second half 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, 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. 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 OraGrowtH210 Trial, a PK/PD trial, the OraGrowtH212 Trial, and a switch trial, the OraGrowtH213 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, anticipating interim analyses of trials, 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 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2022** | **2021** | **2022** | **2021** |
| Revenues: | | | | |
| Royalty revenue | 403 | $ — | $ 514 | $ — |
| Licensing and collaboration revenue | — | 10 | — | 10 |
| Total revenues | 403 | 10 | 514 | 10 |
| Operating expenses: | | | | |
| Research and development | 4,645 | 4,113 | 8,866 | 8,773 |
| General and administrative | 3,682 | 4,561 | 7,303 | 8,518 |
| Total operating expenses | 8,327 | 8,674 | 16,169 | 17,291 |
| Loss from operations | (7,924) | (8,664) | (15,655) | (17,281) |
| Other income and expense: | | | | |
| Other income (expense), net | 6 | (8) | 12 | 12 |
| Interest income | 74 | 2 | 79 | 5 |
| Interest expense | — | — | — | (37) |
| Other income (expense), net | 80 | (6) | 91 | (20) |
| Net loss | $ (7,844) | $ (8,670) | $ (15,564) | $ (17,301) |
| | | | | |
| Net loss per share: | | | | |
| Basic and diluted | $ (0.94) | $ (0.99) | $ (1.86) | $ (2.08) |
| | | | | |
| Weighted average number of common shares outstanding: | | | | |
| Basic and diluted | 8,366,445 | 8,732,149 | 8,361,907 | 8,328,486 |

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

| | June 30, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |

| | | |
|---|---|---|
| Current assets: | | |
| Cash and cash equivalents | $ 79,511 | $ 94,809 |
| Prepaid expenses and other current assets | 5,328 | 4,740 |
| Income tax receivable | 149 | 128 |
| Total current assets | 84,988 | 99,677 |
| Non-current assets: | | |
| Property and equipment, net | 70 | 79 |
| Right-of-use asset | 395 | 556 |
| Total non-current assets | 465 | 635 |
| Total assets | $ 85,453 | $ 100,312 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 854 | $ 612 |
| Accrued expenses | 3,658 | 4,166 |
| Current portion of lease liability | 320 | 352 |
| Total current liabilities | 4,832 | 5,130 |
| Long-term liabilities: | | |
| Royalty obligation payable to Iowa Economic Development Authority | 6,000 | 6,000 |
| Lease liability | 75 | 205 |
| Total long-term liabilities | 6,075 | 6,205 |
| Total liabilities | 10,907 | 11,335 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at June 30, 2022 and December 31, 2021; issued and outstanding shares - 0 at June 30, 2022 and December 31, 2021 | $ — | $ — |
| Common stock, $0.01 par value: Authorized shares - 75,000,000 at June 30, 2022 and December 31, 2021; issued 8,390,915 and 8,366,819 at June 30, 2022 and December 31, 2021, respectively and outstanding shares - 8,377,567 and 8,357,391 at June 30, 2022 and December 31, 2021, respectively | $ 83 | $ 83 |
| Treasury stock, at cost, 13,348 and 9,428 shares at June 30, 2022 and December 31, 2021, respectively | $ (151) | $ (114) |
| Additional paid-in capital | $ 186,599 | $ 185,429 |
| Accumulated deficit | $ (111,985) | $ (96,421) |
| Total stockholders' equity | 74,546 | 88,977 |
| Total liabilities and stockholders' equity | $ 85,453 | $ 100,312 |

Source: Lumos Pharma, Inc.