Lumos Pharma Reports Third Quarter 2021 Financial Results and Provides Clinical Updates

November 3, 2021

- *Majority of OraGrowthH210 Trial sites are open with recent and imminent openings representing historically high enrollment sites*
- *Six-month primary outcome data readout from OraGrowthH210 expected 2H 2023*

AUSTIN, Texas, Nov. 03, 2021 (GLOBE NEWSWIRE) -- Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, announced financial results for the third quarter ending September 30, 2021 and provided an update on clinical programs.

“During our third quarter we continued to advance our LUM-201 program for the treatment of pediatric growth hormone deficiency (PGHD), with the opening of a number of new OraGrowthH210 Trial sites,” said Rick Hawkins, Chairman and CEO of Lumos Pharma. “The screening and enrollment for both our OraGrowthH210 and OraGrowthH212 Trials are progressing well. We continue to expect the primary outcome data readout for our OraGrowthH210 trial in the second half of 2023. Beyond PGHD, we believe LUM-201 represents a pipeline-in-a-product and are encouraged by discussions with KOLs regarding the potential to expand our LUM-201 platform into other indications currently treated by injectable growth hormone.”

Clinical Update:

OraGrowthH210 Trial of LUM-201 in PGHD

Enrollment in the Phase 2 OraGrowthH210 Trial of LUM-201 in PGHD continues, with the majority of the approximately 50 planned sites activated and open for enrollment. OraGrowthH210 is a global clinical trial and is evaluating orally administered LUM-201 in approximately 80 patients diagnosed with PGHD. The objective of the trial is to identify the optimal dose of LUM-201 based on annualized height velocity to be used in a Phase 3 registration trial and to prospectively confirm the preliminary validation of our Predictive Enrichment Marker (PEM) strategy. The Company continues to anticipate six-month data read-out for the OraGrowthH210 Trial in the second half of 2023, with additional 12-month data to be collected.

OraGrowthH212 Trial of LUM-201 in PGHD Initiated Q2 2021

The OraGrowthH212 Trial was initiated in June and is also continuing to enroll patients. OraGrowthH212 is a single site, open-label trial evaluating the pharmacokinetic (PK) and pharmacodynamic (PD) effects of LUM-201 in up to 24 PGHD patients at two dose levels, 1.6 and 3.2 mg/kg/day. Given the open-label design of this trial, the Company has the ability to perform an interim analysis at its discretion. The objective of OraGrowthH212 is to confirm prior clinical data demonstrating the amplified pulsatile release of endogenous growth hormone unique to LUM-201 and its potential for this mechanism of action to contribute to efficacy in PGHD. The primary endpoint is six months of PK/PD and height velocity data, with additional 12-month data to be captured.

LUM-201 Life-Cycle Management

Injectable recombinant human growth hormone (rhGH) and derivative products are currently approved for multiple indications, including PGHD. LUM-201, through its unique mechanism of promoting increased secretion of endogenous GH, may have the potential to be efficacious in many of these indications. Lumos Pharma is in advanced discussions with key opinion leaders and our Clinical and Scientific Advisory Board to expand our LUM-201 pipeline. The Company is actively reviewing the pathway for LUM-201 in other indications including Turner Syndrome, Prader-Willi Syndrome, Idiopathic Short Stature (ISS), and Children Born Small for Gestational Age (SGA).

Financial Results for the Quarter Ended September 30, 2021

- Cash Position – Lumos Pharma ended the third quarter on September 30, 2021, with cash and cash equivalents totaling $100.7 million compared to $98.7 million on December 31, 2020. Cash on hand as of the end of Q3 2021 is expected to support operations through the primary outcome data readout from OraGrowthH210 and OraGrowthH212 Trials.
- R&D Expenses – Research and development expenses were $4.1 million, an increase of $2.0 million for the three months ended September 30, 2021 compared to the same period in 2020, primarily due to increases of $1.8 million in clinical trial and contract manufacturing expenses, $0.4 million in personnel-related expenses and $0.1 million in stock compensation expenses, offset by a decrease of $0.3 million in supplies and other expenses.
- G&A Expenses – General and administrative expenses were $3.4 million, a decrease of $1.8 million for the three months ended September 30, 2021, as compared to the same period in 2020, primarily due to decreases of $1.3 million in personnel-related expenses, $0.3 million in legal, consulting and other expenses and $0.2 million in operating expenses for insurance, rent, supplies, and depreciation.
- Net Loss – The net loss for the third quarter ended September 30, 2021 was $7.5 million compared to net income of $1.8 million for the same period in 2020.
- Lumos Pharma ended Q3 2021 with 8,357,391 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/yxhoo2hz. 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 2891824. 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 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 screening and enrollment for both our OraGrowtH210 and OraGrowtH212 Trials progressing well, expecting the primary outcome data readout for our OraGrowtH210 trial in the second half of 2023, 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 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, 2020, 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Licensing and collaboration revenue	—	74	10	128

Total revenues	—	74	10	128
Operating expenses:				
Research and development	4,112	2,075	12,885	6,743
General and administrative	3,385	5,156	11,903	12,634
Total operating expenses	7,497	7,231	24,788	19,377
Loss from operations	(7,497)	(7,157)	(24,778)	(19,249)
Other income and expense:				
Other income, net	7	6,322	19	6,482
Interest income	2	168	7	246
Interest expense	—	—	(37)	(48)
Other (expense) income, net	9	6,490	(11)	6,680
Net loss before taxes	(7,488)	(667)	(24,789)	(12,569)
Income tax benefit	—	2,432	—	9,321
Net income (loss)	$ (7,488)	$ 1,765	$ (24,789)	$ (3,248)
Accretion of preferred stock to current redemption value	—	—	$ —	(651)
Net income (loss) attributable to common shareholders	$ (7,488)	$ 1,765	$ (24,789)	$ (3,899)
Net income (loss) per share of common stock				
Basic and diluted	$ (0.90)	$ 0.21	$ (2.97)	$ (0.62)
Weighted average number of common shares outstanding				
Basic	8,357,391	8,293,312	8,333,017	6,267,576
Diluted	8,357,391	8,486,804	8,333,017	6,267,576

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 100,650	$ 98,679
Prepaid expenses and other current assets	4,988	3,506
Income tax receivable	116	115
Other receivables	—	26,149
Total current assets	105,754	128,449
Non-current assets:		
Property and equipment, net	75	335
Right-of-use asset	636	249
Total non-current assets	711	584
Total assets	$ 106,465	$ 129,033
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 149	$ 244
Accrued expenses	5,555	5,898
Current portion of lease liability	349	319
Total current liabilities	6,053	6,461
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	288	—
Total long-term liabilities	6,288	6,000
Total liabilities	12,341	12,461
Commitments and contingencies:		
Stockholders' equity:		

Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at September 30, 2021 and December 31, 2020; issued and outstanding shares - 0 at September 30, 2021 and December 31, 2020	$	—	$	—
Common stock, $0.01 par value: Authorized shares - 75,000,000 at September 30, 2021 and December 31, 2020; issued 8,366,819 and 8,305,269 at September 30, 2021 and December 31, 2020, respectively and outstanding 8,357,391 and 8,305,269 at September 30, 2021 and December 31, 2020, respectively	$	83	$	83
Treasury stock, at cost, 9,428 and 0 at September 30, 2021 and December 31, 2020, respectively	$	(114)	$	—
Additional paid-in capital	$	184,935	$	182,480
Accumulated deficit	$	(90,780)	$	(65,991)
Total stockholders' equity		94,124		116,572
Total liabilities and stockholders' equity	$	106,465	$	129,033

Source: Lumos Pharma, Inc.