Lumos Pharma Announces the Initiation of Phase 2b OraGrowthH210 Trial and Reports Third Quarter 2020 Financial Results

November 10, 2020

- *Lumos Pharma has initiated Phase 2b OraGrowthH210 Trial evaluating oral LUM-201 in pediatric growth hormone deficiency (PGHD) patients with data read-out anticipated mid-year 2022*

AUSTIN, Texas, Nov. 10, 2020 (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 ended September 30, 2020 and provided an update on clinical activities.

“This past quarter was marked by significant achievements leading to the initiation of our Phase 2b OraGrowthH210 Trial evaluating oral LUM-201 in pediatric growth hormone deficiency patients and the previously announced sale of our PRV in July,” commented Rick Hawkins, Chairman, CEO and President of Lumos Pharma. “We are thrilled to advance our LUM-201 program and look forward to building upon this momentum as we continue our efforts to expand our business and pipeline.”

Corporate Updates

- **Initiation of Phase 2b OraGrowthH210 Trial** - Lumos Pharma announced the initiation of its Phase 2b OraGrowthH210 trial evaluating oral LUM-201 in pediatric growth hormone deficiency (PGHD) patients. The trial will evaluate three dose levels of LUM-201 in PGHD patients against a comparator arm of standard-of-care injectable growth hormone therapy. Dosing will be administered over six months, with annualized growth height velocity as the primary clinical outcome measure. The purpose of this trial will be to prospectively confirm our Predictive Enrichment Marker (PEM) strategy and to identify the optimal dose of LUM-201 to be used in a registration trial. The Company anticipates data read out for the OraGrowthH210 Trial mid-year 2022.
- **Received First Tranche of PRV Sale Funds** - Lumos received the first tranche of $34 million from the total $60 million due to the Company from the PRV sale and anticipates the receipt of the second tranche of $26 million in Q1 2021. We anticipate these funds will serve as additional capital to support the expansion of the Company’s pipeline through the licensure of another novel therapeutic candidate for those suffering from rare diseases.
- **Pharmacokinetic/Pharmacodynamic OraGrowthH212 Trial of LUM-201 in PGHD Remains on Track** - The Company continues to prioritize the initiation of its second concurrent trial of LUM-201 in PGHD and remains on track to initiate the OraGrowthH212 Trial in Q1 2021.

Financial Results for the Three-Month Period Ended September 30, 2020

- Cash Position: Lumos Pharma ended the quarter on September 30, 2020, with cash and cash equivalents totaling $105.6 million compared to Lumos Pharma prior to its merger with NewLink Genetics cash of $5.0 million December 31, 2019 and pro forma December 31, 2019 cash of $95.5 million, inclusive of NewLink Genetics. The Company expects its cash on hand is sufficient to fund current operations through the read-out of our Phase 2b OraGrowthH210 Trial and completion of the OraGrowthH212 Trial.
- R&D Expenses: Research and development expenses for the three months ended September 30, 2020 were $2.1 million, an increase of $0.9 million from $1.2 million for the same period in 2019. The increase is primarily due to increases of $0.7 million in clinical trial expenses, $0.2 million in personnel-related and stock compensation expenses, $0.2 million in supplies and other expenses and $0.1 million in legal expenses, offset by a decrease of $0.3 million in contract manufacturing expense.
- G&A Expenses: General and administrative expenses for the three months ended September 30, 2020 were $5.2 million, an increase of $3.7 million from $1.5 million for the same period in 2019. The increase was due primarily to increases of $2.6 million in personnel-related and stock compensation expenses and $1.1 million in operating expenses for insurance, rent, supplies, and depreciation expenses.
- Net Income (Loss): The net income for the three months ended September 30, 2020 was $1.8 million compared to a net loss of $2.7 million for the same period in 2019.
- Lumos Pharma ended Q3 2020 with 8,293,312 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 and business development activities. 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 www.lumos-pharma.com in the "Investors & Media" section under "Events and Presentations" or through this link: https://edge.media-server.com/mmc/p/upsndx4s. 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 1076873. 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 for the treatment of Pediatric Growth Hormone Deficiency (PGHD). If approved by the FDA, LUM-201 would provide an orally administered alternative to daily injections that current PGHD patients endure for many years of treatment. LUM-201 has received Orphan Drug Designation in both the US and EU. For more information, please visit www.lumos-pharma.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of Lumos Pharma, Inc. (the "Company") 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. The words "forecast," "projected," "guidance," "upcoming," "will," "would," "plan," "intend," "anticipate," "approximate," "expect," "potential," "imminent," or the negative of these terms or other similar expressions are intended to ident ify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, our intent to initiate a Pharmacokinetic/Pharmacodynamic OraGrowthH212 study of LUM-201 in PGHD in 2021, anticipated monetization of our priority review voucher, that cash on hand is expected to fund current operations through the read-out of our Phase 2b OraGrowthH210 Trial and completion of the OraGrowthH212 Trial, that we are engaging in activities that we hope will lead to the expansion of our pipeline through the licensure of other rare disease assets, that we believe Lumos Pharma is well positioned to execute on our clinical and business development plans, the potential of an orally administered treatment regimen for PGHD and other indications, plans related to 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 its operating requirements; and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that the Company makes due to a number of important factors, including the effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic, the outcome of our future interactions with regulatory authorities, the outcome of our Phase 2b OraGrowthH210 Trial for LUM-201, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the availability of sufficient resources for our operations and to conduct or continue planned clinical development programs, the ability to obtain the necessary patient enrollment for our product candidate in a timely manner, the ability to successfully develop our product candidate, the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as LUM-201 that are safe and effective for use as human therapeutics, the timing and ability of Lumos to monetize its priority review voucher and 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 as discussed in "Risk Factors" and elsewhere in Lumos Pharma's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, the Company's Annual Report on Form 10-K for the year ended December 31, 2019 and other reports filed with the SEC. The forward-looking statements in this press release represent the Company's views as of the date of this pre ss release. The Company anticipates that subsequent events and developments will cause their views to change. However, while it may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing the Company's 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,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Licensing and collaboration revenue	$ 74	$ —	$ 128	$ —
Total revenues	74	—	128	—
Operating expenses:				
Research and development	2,075	1,202	6,743	4,538
General and administrative	5,156	1,496	12,634	2,893
Total operating expenses	7,231	2,698	19,377	7,431
Loss from operations	(7,157)	(2,698)	(19,249)	(7,431)
Other income and expense:				

Other income, net	6,322	—	6,482	23
Interest income	168	29	246	65
Interest expense	—	—	(48)	—
Other income, net	6,490	29	6,680	88
Net loss before taxes	(667)	(2,669)	(12,569)	(7,343)
Income tax benefit	2,432	—	9,321	—
Net income (loss)	$ 1,765	$ (2,669)	$ (3,248)	$ (7,343)
Accretion of preferred stock to current redemption value	—	(766)	(651)	(2,274)
Net income (loss) attributable to common shareholders	$ 1,765	$ (3,435)	$ (3,899)	$ (9,617)
Net income (loss) per share of common stock				
Basic	$ 0.21	$ (2.56)	$ (0.62)	$ (7.15)
Diluted	$ 0.21	$ (2.56)	$ (0.62)	$ (7.15)
Weighted average number of common shares outstanding				
Basic	8,293,312	1,343,483	6,267,576	1,344,755
Diluted	8,486,804	1,343,483	6,267,576	1,344,755

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

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 105,575	$ 4,952
Prepaid expenses and other current assets	3,230	82
Income tax receivable	174	—
Other receivables	26,176	35
Total current assets	135,155	5,069
Non-current assets:		
Property and equipment, net	594	84
Right-of-use asset	439	373
Total non-current assets	1,033	457
Total assets	$ 136,188	$ 5,526
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 137	$ 365
Accrued expenses	6,293	709
Current portion of lease liability	535	189
Total current liabilities	6,965	1,263
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	—
Lease liability	35	191
Deferred tax liability	4,653	—
Total long-term liabilities	10,688	191
Total liabilities	17,653	1,454
Commitments and contingencies:		
Redeemable convertible preferred stock:		
Series A redeemable convertible preferred stock, $0.0001 par value: Authorized, issued and outstanding shares — 0 and 978,849 at September 30, 2020 and December 31, 2019, respectively	—	21,904
Series B redeemable convertible preferred stock, $0.0001 par value: Authorized, issued and outstanding shares — 0 and 1,989,616 at September 30, 2020 and December 31, 2019, respectively		41,631
Stockholders' equity (deficit):		
Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at September 30, 2020 and December 31, 2019, respectively; issued and outstanding shares —0 at September 30, 2020 and December 31, 2019	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 and 36,000,000 at September 30, 2020 and December 31, 2019; issued and outstanding 8,293,312 and 1,177,933 at September 30, 2020 and December 31, 2019, respectively	83	12

Additional paid-in capital	182,028		202	
Accumulated deficit	(63,576	)	(59,677	)
Total stockholders' equity (deficit)	118,535		(59,463	)
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 136,188		$ 5,526	

Source: Lumos Pharma, Inc.