Lumos Pharma Reports Second Quarter 2020 Results and Provides Update on Clinical and Corporate Activities

August 13, 2020

- *Lumos Pharma sells Priority Review Voucher (PRV), valued at $100 million - Lumos Pharma to receive $60 million for its 60% interest in PRV*
- *Lumos Pharma reaffirms its expectation of the initiation of its Phase 2b LUM-201 trial in Pediatric Growth Hormone Deficiency (PGHD) prior to the end of 2020*

AUSTIN, Texas, Aug. 13, 2020 (GLOBE NEWSWIRE) -- Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, announced financial results for the second quarter ended June 30, 2020 and provided an update on clinical activities.

"The second quarter continued to be a busy and productive one for Lumos Pharma," commented Rick Hawkins, Chairman, CEO and President. "Most notably, the efforts of our team during this period culminated in the sale of our Priority Review Voucher in line with our expectations, further strengthening our balance sheet. With a Study May Proceed letter from the FDA in hand, we are progressing toward our goal of initiating the Phase 2b trial of LUM-201, our oral therapeutic candidate for PGHD, prior to the end of this year. In addition, we continue to engage in activities to expand our pipeline through the licensure of other rare disease assets. With our strong balance sheet and non-dilutive funds from the monetization of our PRV, we believe Lumos Pharma is well positioned to execute on our clinical and business development plans."

Corporate Update

Sale of Priority Review Voucher (PRV) - On July 27, 2020, Lumos Pharma announced that it had entered into a definitive agreement to sell its PRV to Merck, known as MSD outside the United States and Canada. The PRV was granted in conjunction with the approval by the U.S. Food and Drug Administration (FDA) of ERVEBO®, a vaccine developed by the Company's licensee, Merck, for the prevention of the Zaire Ebola virus disease.

Under the terms of the original license agreement, Lumos Pharma is entitled to retain 60% of the value of the PRV. Based upon an agreed valuation of $100 million, Merck will pay Lumos $60 million. The $60 million will be received in two non-contingent payments, $34 million anticipated in the third quarter of 2020, and $26 million in the first quarter of 2021. The transaction remains subject to customary closing conditions including anti-trust review. The non-dilutive funds from this transaction will provide additional capital to support the expansion of the Company's pipeline through the in-licensing or acquisition of another novel therapeutic candidate for those suffering from rare diseases.

Clinical Update and COVID-19 Impact

Phase 2b trial of LUM-201 in PGHD - Lumos Pharma continues to prioritize the clinical development of LUM-201, its orally administered therapeutic candidate for a significant subset of children with PGHD. The Company continues to anticipate the initiation of its Phase 2b trial in PGHD prior to the end of 2020. This 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 strategy and to identify the optimal dose of LUM-201 to be used in a registration trial.

While the coronavirus pandemic initially caused pervasive interruptions to clinical trials industrywide, clinical sites have begun to reopen, and numerous trials have restarted. A resurgence of the coronavirus pandemic may cause further delays or shutdowns of clinical trials, including our own. Our Phase 2b site selection, however, spans a broad geographic base across the US and multiple other countries and includes both private clinics and academic centers, which we believe should help mitigate the impact of a resurgence of this pandemic.

Pharmacokinetic/Pharmacodynamic Study of LUM-201 in PGHD - Lumos also plans to initiate a second concurrent trial of LUM-201 in PGHD by Q1 2021. This trial is intended to further explore the effects of the mechanism of action of LUM-201 in amplifying the natural pulsatile secretion of growth hormone. The study will focus on pharmacodynamic and pharmacokinetic endpoints at two different doses in a limited number of children with PGHD, corroborating the amplified pulsatile secretion demonstrated in prior LUM-201 studies in adults. The trial will be conducted at a single specialized pediatric center with the capacity to conduct the more frequent sample acquisition and monitoring required for these types of clinical trials. This study will run in parallel with our announced Phase 2b trial with the intention that the data will be supportive in any future regulatory filings.

Pipeline Expansion - The Company continues to pursue business development opportunities to expand its rare disease portfolio. With a team possessing deep experience in the rare disease sector, we believe we are well-positioned to be successful in our pursuit of opportunities to expand our pipeline and build shareholder value.

Financial Results for the Three-Month Period Ended June 30, 2020 and Updated Cash Guidance

Cash Position: Lumos Pharma ended the quarter on June 30, 2020, with cash and cash equivalents totaling $72.7 million compared to Lumos Pharma prior to its merger with NewLink Genetics cash of $5.0 million on December 31, 2019 and pro forma cash, including NewLink Genetics, of $95.5 million on December 31, 2019. The Company expects its cash on hand will be sufficient to fund current operations through the Phase 2b LUM-201 trial read-out.

R&D Expenses: Research and development expenses for the three months ended June 30, 2020 were $2.8 million, an increase

of $882,000 from $1.9 million for the same period in 2019. The increase is primarily due to an increase of $877,000 in personnel-related and stock compensation expense, an increase of $480,000 in clinical trial expense and an increase of $310,000 in supplies and other expense, offset by a decrease of $430,000 in contract manufacturing expense, and a decrease of $355,000 in legal and consulting expense.

G&A Expenses: General and administrative expenses for the three months ended June 30, 2020 were $4.1 million, an increase of $3.4 million from $714,000 for the same period in 2019. The increase was due primarily to increases of $1.2 million in personnel-related and stock compensation expense, $1.2 million due to increased operating expenses for insurance, rent, supplies and depreciation, and $969,000 in legal and consulting expense.

Net Loss: The net loss for the three months ended June 30, 2020 was $5.4 million compared to a net loss of $2.6 million for the same period in 2019.

Lumos Pharma ended Q2 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/ahe2owxg. 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 9585725. 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 identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, that we expect to initiate our Phase 2b LUM-201 trial prior to the end of 2020, our intent to initiate a Pharmacokinetic/Pharmacodynamic study of LUM-201 in PGHD in 2021, the closing of the sale of our priority review voucher, that cash on hand is expected to fund current operations through the Phase 2b trial-readout, 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 clinical 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 of the closing of the sale of the PRV and our ability 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 as discussed in "Risk Factors" and elsewhere in Lumos Pharma's Quarterly Report on Form 10-Q for the quarter ended March 31, 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 press 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 June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Licensing and collaboration revenue	$ 33	$ —	$ 55	$ —
Total revenues	33	—	55	—
Operating expenses:				
Research and development	2,763	1,881	4,669	3,336
General and administrative	4,147	714	7,478	1,397
Total operating expenses	6,910	2,595	12,147	4,733
Loss from operations	(6,877)	(2,595)	(12,092)	(4,733)
Other income and expense:				
Miscellaneous income, net	24	26	161	59
Interest income	74	—	79	—
Interest expense	—	—	(50)	—
Other income, net	98	26	190	59
Net loss before taxes	(6,779)	(2,569)	(11,902)	(4,674)
Income tax benefit	1,426	—	6,889	—
Net loss	$ (5,353)	$ (2,569)	$ (5,013)	$ (4,674)
Accretion of preferred stock to current redemption value	—	(758)	(651)	(1,508)
Net loss attributable to common shareholders	$ (5,353)	$ (3,327)	$ (5,664)	$ (6,182)
Basic and diluted loss per share	$ (0.65)	$ (2.47)	$ (1.08)	$ (4.59)
Basic and diluted average shares outstanding	8,292,809	1,345,402	5,243,577	1,345,402

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

	June 30, 2020	**December 31, 2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 72,697	$ 4,952
Prepaid expenses and other current assets	5,158	82
Income tax receivable	4,666	—
Other receivables	296	35
Economic interest in Priority Review Voucher, held for sale	87,920	—
Total current assets	170,737	5,069
Property and equipment, net	834	84
Right-of-use asset	627	373
Total non-current assets	1,461	457
Total assets	$ 172,198	$ 5,526
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 155	$ 365
Accrued expenses	5,944	709
PRV related liability, held for sale	35,720	—
Current portion of lease liability	731	189
Current portion of notes payable and obligations under capital leases	11	—
Total current liabilities	42,561	1,263
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	—
Lease liability	88	191
Deferred tax liability	7,084	—

Total long-term liabilities	13,172	191
Total liabilities	55,733	1,454
Commitments and contingencies:		
Series A redeemable convertible preferred stock, $0.0001 par value: Authorized, issued and outstanding shares — 0 and 978,849 at June 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 June 30, 2020 and December 31, 2019, respectively		41,631
Stockholders' equity (deficit):		
Blank check preferred stock, $0.01 par value: Authorized shares - 5,000,000 at June 30, 2020 and December 31, 2019, respectively: issued and outstanding shares —0 at March 31, 2020 and December 31, 2019	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 and 36,000,000 at June 30, 2020 and December 31, 2019; issued and outstanding 8,293,312 and 1,177,933 at June 30, 2020 and December 31, 2019, respectively	83	12
Additional paid-in capital	181,723	202
Accumulated deficit	(65,341)	(59,677)
Total stockholders' equity (deficit)	116,465	(59,463)
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 172,198	$ 5,526

Source: Lumos Pharma, Inc.