UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 13, 2020

LUMOS PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction

of incorporation)

001-35342 (Commission File Number) 42-1491350 (IRS Employer Identification No.)

4200 Marathon Blvd., Suite 200 Austin, TX 78756

(Address of principal executive offices)

Registrant's telephone number, including area code: (512) 215-2630

Not applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered				
Common Stock	LUMO	The Nasdaq Stock Market				

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter). o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act o

Item 2.02. Results of Operations and Financial Condition.

On August 13, 2020, Lumos Pharma, Inc., a Delaware corporation (the "Company"), issued a press release providing an operational update and reporting financial results for the second quarter ended June 30, 2020 ("Press Release").

A copy of the Press Release and the Second Quarter 2020 Financial Results Presentation are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

The information in this Current Report, including Exhibits 99.1 and 99.2 attached hereto are furnished under Item 2.02 of this report and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

Section 9 - Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated August 13, 2020, entitled "Lumos Pharma Reports Second Quarter 2020 Results and Provides Update on Clinical and Corporate Activities"
99.2	Second Quarter 2020 Financial Results Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: August 13, 2020

LUMOS PHARMA, INC., a Delaware corporation

By: <u>/s/ Richard J. Hawkins</u> Richard J. Hawkins

Its:

Chief Executive Officer



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

- 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, TX, August 13, 2020 - 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 <u>www.lumos-pharma.com</u> in the "Investors & Media" section under "Events and Presentations" or through this link: <u>https://edge.media-server.com/mmc/p/ahe2owxg</u>. 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 <u>www.lumos.pharma.com</u>.

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 include, among others, that we expressions are intended to identify forward-looking statements, although not all forward-looking statements in the meaning of the sel 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 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 availability of sufficient for use as believe on ur product candidate in a timely manner, the ability to successfully develop our product candidate, the risks associated with the process of development; programs, the ability to a successfully develop our product candidate, the risks associated with the proc

###

Investor & Media Contact:

Lisa Miller Lumos Pharma Investor Relations 512-648-3757 ir@lumos-pharma.com



Lumos Pharma, Inc. Condensed Consolidated Statements of Operations (unaudited) (In thousands, except share and per share amounts)

	Three Months Ended June 30,		ne 30,	Six Months Ended June 30,			e 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 3: 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
	_		-	



Second Quarter 2020 Financial Results and Corporate Update

August 13, 2020

Lumos Pharma Q2 2020 Conference Call



Forward Looking Statements

This presentation contains forward-looking statements of Lumos Pharma, Inc. that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation are forward-looking statements, within the mea The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan, "target," "potential," "will," "could," "should," "seek" or the negative of these terms or other similar expressions are intended to iden forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among others, statements regarding the expected initiation of a Phase 2b clinical trial, sufficiency of funding for such trial, the potential of an orally administered treatment regimen for PGHD and other indications, projecash position and its sufficiency to fund the company's operations through data read-out for the Phase 2b trial of LUM-201 in PGE expected initiation of a Pharmacokinetic/Pharmacodynamic trial of LUM-201 in PGHD by Q1 2021; impact of regulatory feedback clinical timelines and costs, results of its clinical trials for product candidates; its timing of release of data from ongoing clinical sturplans related to execution of clinical trials; plans related to moving additional indications into clinical development; milestones or ceconomic interests, Lumos Pharma's financial guidance for 2020 and beyond; and any other statements other than statements of fact.

Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that Lumos Pharma makes due to a number of important factors, including the effects of pandemics or other widespread health pr such as the ongoing COVID-19 pandemic and those risks discussed in "Risk Factors" and elsewhere in Lumos Pharma's Annual I on Form 10-K for the year ended December 31, 2019, Form 10-Q for the quarter ended March 31, 2020, and other reports filed wi the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this presentation represent Lumos Pharma views as of the date of this presentation. Lumos Pharma anticipates that subsequent events and developments will cause its view change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaim obligation to do so. You should, therefore, not rely on these forward-looking statements as representing Lumos Pharma's views as date subsequent to the date of this presentation. Large Nature 100 March 200 March 200

Corporate Update - Sale of Priority Review Voucher (PRV)

- July 27, 2020 Merck and Lumos Pharma sign agreement for the sa the PRV issued in conjunction with approval of Ebola vaccine
- Agreed upon value of PRV set at \$100 million
- Lumos Pharma to be paid \$60 million for its 60% interest in PRV
- PRV proceeds represent non-dilutive funds available for Lumos Pha to expand portfolio of rare disease assets

Clinical and Business Development Activities

- Clinical-stage company focused on therapeutics for rare diseases
- Lead asset, LUM-201, with potential to disrupt established pediatric growth hormone deficiency (PGHD) market of over \$1 Billion*
 - LUM-201 oral therapeutic with potential to supplant significant segment standard-of-care injectable PGHD market
- Phase 2b trial of LUM-201 in PGHD expected to begin before end of
- Pharmacokinetic/Pharmacodynamic study of LUM-201 in PGHD
 - Concurrent study to begin by Q1 2021

5

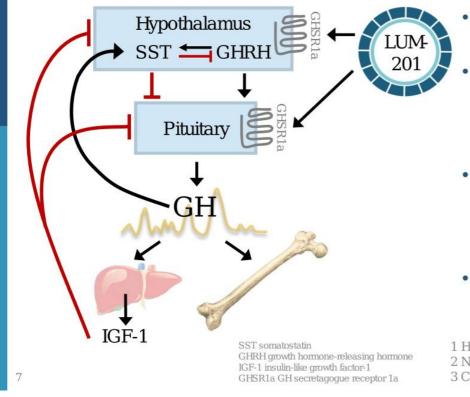
Pursuit of additional rare disease assets to expand pipeline

* USA, Germany, France, Italy, Spain, UK, Japan (Global Data Opportunity Analyzer: Growth Hormone Deficiency Opportunity Analysis and Forecasts to GDHC069POA, May 2017) lur

PGHD and Standard of Care

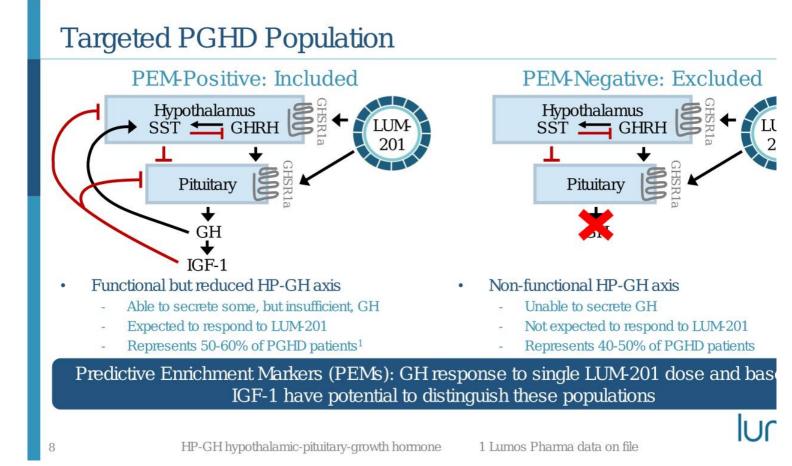
- PGHD occurs due to inadequate secretion of growth hormone by the pituitary gland during childhood PGHD can be either hereditary or acquired, although the majority of cases have unknown causes (idiopathic) versus Lack of physical growth is the most obvious manifestation; but numerous metabolic processes are also affected PGHD incidence in U.S. approximately 1 in 3500 children¹ Standard of care consists of daily, subcutaneous injections of recombinant human growth hormone (rhGH) Can be painful, potentially leading to missed doses and sub-optimal growth^{2,3} ~2500 injections over years of treatment Robust, established market primed for an oral alternative 1 GlobalData EpiCast Report for Growth Hormone Deficiency Epidemiology forecast to 2026 lur 2 Rosenfeld 2008 Endocrine Practice
 - 3 Cutfield 2011 PLOS ONE

LUM-201 Mechanism of Action



- Oral LUM-201 is a growth hormone (GH) secretagogu
- Acts as an agonist of GH Secretagogue Receptor (GHSR1a) to stimulate GH release¹
- LUM-201 has been observe increase the amplitude of endogenous pulsatile GH secretion^{2,3}
- LUM-201's stimulatory effec regulated by GH/IGF-1 feed
- 1 Howard 1996 Science 2 Nass 2008 Ann Intem Med
- 3 Chapman 1997 J Clin Endocrinol Metab





Phase 2b Trial of LUM-201 in PGHD

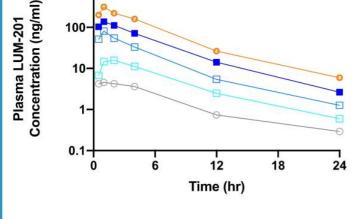
- Two main goals set for Phase 2b
 - Prospectively confirm the utility of PEM strategy
 - Determine the optimal dose for Phase 3 registration trial
- Phase 2b PGHD clinical trial design
 - Three dose levels of LUM-201 (0.8, 1.6, 3.2 mg/kg)
 - Positive control arm of daily rhGH injections
 - Treatment-naïve, age-matched cohorts; 6-month dosing
 - Primary outcome measure: annualized growth height velocity
- Anticipate initiation of Phase 2b trial prior to the end of 2020

Generate safety and efficacy data to move on to Phase 3 study

lur

PK/PD Response Supports Proposed Doses in PGHD

Pharmacokinetics Dose response to 5.6 mg/kg PGHD dose equivalent*

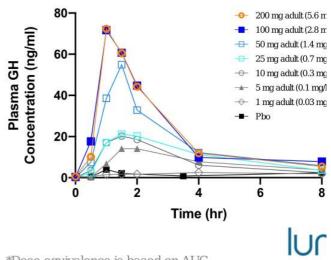


10

Merck Study 001 in healthy adult subjects

Pharmacodynamics

 PD plateau possible ≥ 2.8 m PGHD dose equivalent*



*Dose equivalence is based on AUC

Pharmacokinetic / Pharmacodynamic Trial of LUM-201 in PGF

- Purpose of Pharmacokinetic/Pharmacodynamic (PK/PD) trial
 - Further explore LUM-201's mechanism of amplification of natural pulsati secretion of growth hormone
 - To expand data package in support of future regulatory filings
- PK/PD clinical trial design
 - Two dose levels of LUM-201
 - Single-site, 6-month, open-label study in treatment naïve PGHD patient:
 - Concurrent with Phase 2b trial of LUM-201 in PGHD
- Anticipate initiation of PK/PD trial by Q1 2021

Generate additional data to support future regulatory filings

lur

LUM-201: Other Potential Rare Endocrine Disorders

 Beyond PGHD, Lumos Pharma also plans to investigate LUM-201 for other rare endocrine disorders, for which rhGH has been approved



lur

Significant opportunities with established regulatory pathways

GARD: Genetic and Rare Diseases Information Center

Secure Cash Position

Metric	Position				
Cash balance on June 30, 2020	\$72.7 million				
Additional non-dilutive resources anticipated	\$60 million for 60% interest in PRV valu \$100 million J uly 2020 ¹				
Projected cash use per quarter through 2020	~\$6.5 to \$7.5 million				
Shares outstanding as of J une 30, 2020	~8.3 million				
J une 30, 2020 cash balance expected to be sufficient to fund curren operations through Phase 2b trial data read-out					
13 ¹ Accement to monetize PRV announced Luby					

 $^{\rm 1}$ Agreement to monetize PRV announced J uly 27, 2020

13

Lumos Pharma: Summary of Investment Thesis



Potential to significantly increase shareholder value

lur