

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): March 9, 2021

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):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- 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).

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

Section 2 - Financial Information

Item 2.02. Results of Operations and Financial Condition.

On March 9, 2021, Lumos Pharma, Inc., a Delaware corporation (the "Company"), issued a press release reporting financial results for the year ended December 31, 2020 (the "Press Release").

A copy of the Press Release and the Year End 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 March 9, 2021, entitled " Lumos Pharma Reports Full Year 2020 Financial Results and Provides Update on OraGrowth Trials in PGHD "
99.2	Year End 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: March 9, 2021

LUMOS PHARMA, INC.,
a Delaware corporation

By: /s/ Richard J. Hawkins
Richard J. Hawkins
Its: Chief Executive Officer



Lumos Pharma Reports Full Year 2020 Financial Results and Provides Update on OraGrowth Trials in PGHD

- Data published in the *Journal of Endocrine Society* and accepted for presentation at ENDO 2021 demonstrate distinct mechanism of action and potential efficacy of LUM-201 in subset of pediatric growth hormone deficiency (PGHD) patients
 - Final tranche of \$26 million non-dilutive funds from PRV sale received in January 2021

AUSTIN, TX, March 9, 2021 - Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, announced financial results for the year ended December 31, 2020 and provided an update on clinical activities and financial guidance for 2021.

“The fourth quarter and full year 2020 were marked by significant achievements for Lumos Pharma,” commented Rick Hawkins, Chairman, CEO and President of Lumos Pharma. “From the completion of our merger last spring, the subsequent sale of our PRV providing significant non-dilutive funds, to the initiation of our Phase 2b OraGrowth210 Trial evaluating our orally administered therapeutic for PGHD, Lumos Pharma has built a solid foundation to advance our clinical and corporate strategy targeting PGHD, diseases of growth hormone deficiency, and other rare diseases in the coming year.”

Clinical Updates

- **LUM-201 Data Published in Journal of Endocrine Society (JES)** – The manuscript, “*Development of a Predictive Enrichment Marker for Oral GH Secretagogue LUM-201 in Children with Growth Hormone Deficiency*,” by Bright, G., MD, *et al*, was published in the *Journal of Endocrine Society* late February. This peer-reviewed analysis of data from prior studies of LUM-201 in pediatric growth hormone deficiency (PGHD) supports the utility of specific predictive enrichment markers (PEMs) in identifying PGHD patients likely to respond to LUM-201. The two PEMs identified after a single dose of LUM-201, baseline IGF-1 cut-off level > 30 ng/ml and peak GH level \geq 5 ng/mL, are being used to qualify PGHD patients for enrollment in our OraGrowth210 Trial.
- **Predictive Enrichment Markers Define Subset of Moderate Growth Hormone Deficiency** – The manuscript, “*Corroboration Between Prediction Enrichment Markers for Height Velocity to rhGH and an Oral GH Secretagogue Treatment in Children with Moderate GHD*,” by Blum, W., PhD, *et al*, was published in the *Journal of Endocrine Society* late February. This peer-reviewed analysis of data on children with growth hormone deficiency (GHD) in a large legacy database (GeNeSIS data) corroborates that approximately 60% of the total pediatric GHD patient population meet the definition of moderately GHD deficient (PEM-positive) and are likely to respond to a growth hormone secretagogue.
- **Poster to be Presented at ENDO 2021** – The poster entitled, “*LUM-201 Elicits Greater GH Response than Standard GH Secretagogues in Pediatric Growth Hormone Deficiency*,” (abstract 7102) will be presented at the Endocrine Society 2021 Annual Meeting, March 20th-23rd.
- **Phase 2b OraGrowth210 Trial Advances** – The Phase 2b OraGrowth210 Trial initiated in Q4 2020 continues to advance. This global Phase 2b trial will evaluate orally administered LUM-201 in approximately 80 patients diagnosed with PGHD. 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 Phase 3 registration trial. The Company continues to anticipate data read-out for the OraGrowth210 Trial mid-year 2022.

- **OraGrowth212 Trial (PK/PD study) of LUM-201 in PGHD Initiation Anticipated Q2 2021** - This study will evaluate the pharmacokinetic and pharmacodynamic (PK/PD) effects of two dose levels of LUM-201 (1.6 and 3.2 mg/kg/day) in approximately 24 PGHD patients at a single specialized clinical site. The purpose of this study will be to confirm prior preclinical and clinical data supporting the increased pulsatile release of endogenous growth hormone peaks that characterizes the unique mechanism of action of LUM-201. Recently we were informed of a fire at the San Borja Arriaran Hospital in Santiago, Chile, which is the location of the OraGrowth212 trial. While we had originally expected to initiate this trial in Q1 2021, we now anticipate the initiation of the OraGrowth212 Trial to occur in Q2 2021 due to potential delays as the hospital addresses this incident. Our investigator's clinic was not directly involved in the fire, and we continue to work with our local contacts to advance the trial. As we have previously stated, this trial is not on the critical path for regulatory approval of LUM-201, and we do not anticipate the fire will cause any delays to our previously stated regulatory approval timeline. We are exploring alternate sites to conduct the trial in the event that the original site is unable to proceed in a timely manner.
- **OraGrowth211 Trial, a Long-Term Extension Study, is Announced** – Lumos Pharma announced the OraGrowth211 Trial, an extension study to determine the long-term safety, PK/PD markers and growth outcomes attributable to LUM-201 administered to children with growth hormone deficiency. The OraGrowth211 Trial will be open to all eligible PGHD patients who have completed OraGrowth210, OraGrowth212 or other subsequent LUM-201 trials.
- **Business Development** – The Company continues to pursue opportunities to expand our rare disease pipeline through the in-licensure or acquisition of another novel therapeutic candidate for those suffering from rare diseases.

Corporate Updates

- **Received Final Tranche of Funds from PRV Sale** – In January 2021, Lumos received the second and final tranche of \$26.0 million from the total \$60.0 million due to the Company from the PRV sale. We anticipate these funds will serve as additional capital to support the expansion of the Company's pipeline through its business development efforts.
- **Financial Guidance for 2021** – The Company anticipates average cash use of approximately \$8.0 to \$9.0 million per quarter through 2021.
- **Management Changes** – As previously disclosed, Eugene Kennedy, MD, Chief Medical Officer (CMO), departed Lumos Pharma March 4, 2021 to join a privately held company focused on developing therapeutics for patients suffering from cancer. Lumos Pharma will conduct a search for his replacement. John McKew, PhD, COO and CSO together with George Bright, MD, VP, Clinical Development and a pediatric endocrinologist, will cover all CMO responsibilities in the interim.
- **Appointed New Board Member with Rare Disease Background** – February 16, 2021, Lumos Pharma announced the appointment of new Board member, An van Es-Johansson, M.D., with a wealth of experience in rare diseases. Dr. van Es-Johansson recently served as the Chief Medical Officer and Head of Development for AlzeCure Pharma, a Swedish pharmaceutical company with a primary focus on Alzheimer's disease, where she now serves as a senior advisor. Dr. van Es-Johansson's early work in the life science industry focused on the clinical development of recombinant human growth hormone (rhGH) therapeutics for Turner Syndrome and other endocrine disorders at both Eli Lilly and Pharmacia Upjohn. Since then, Dr. van Es-Johansson has held leadership roles at several large and small biopharmaceutical companies and currently serves on the Board of Directors at Medivir AB, Savara Pharmaceuticals, PLUS Therapeutics, and Agendia BV. Dr. van Es-Johansson received a M.D. from Erasmus University, Rotterdam, The Netherlands.

Financial Results for the Year Ended December 31, 2020

- Cash Position – Lumos Pharma ended the year on December 31, 2020, with cash and cash equivalents totaling \$98.7 million compared to \$5.0 million on 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 OraGrowtH210 Trial and completion of the OraGrowtH212 Trial.
- R&D Expenses – Research and development expenses for the year ended December 31, 2020 were \$9.2 million, an increase of \$3.5 million from \$5.7 million for the same period in 2019. The increase is primarily due to increases of \$2.4 million in clinical trial expenses, \$1.4 million in personnel-related and stock compensation expenses, \$0.8 million in supplies and other expenses and \$0.4 million in write-off of the acquired NewLink's in-process research and development costs, offset by a decrease of \$1.5 million in contract manufacturing expense.
- G&A Expenses – General and administrative expenses for the year ended December 31, 2020 were \$17.3 million, an increase of \$13.1 million from \$4.2 million for the same period in 2019. The increase was due primarily to increases of \$7.0 million in personnel-related and stock compensation expenses, \$4.2 million in operating expenses for insurance, rent, supplies, and depreciation expenses, \$1.6 million due to the Merger related expenses and \$0.6 million in legal and consulting expenses, offset by a decrease of \$0.3 million in travel expenses.
- Net Loss – The net loss for the year ended December 31, 2020 was \$5.7 million compared to a net loss of \$9.7 million for the same period in 2019.
- Lumos Pharma ended Q4 2020 with 8,305,269 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 <https://lumos-pharma.com/> in the "Investors & Media" section under "Events and Presentations" or through this link: <https://edge.media-server.com/mmc/p/6ujteayr>. 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 3735869. 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 2b clinical trial, the OraGrowtH210 Trial, 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 <https://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, our intent to initiate a Pharmacokinetic/Pharmacodynamic OraGrowtH212 study of LUM-201 in PGHD in 2021, our intent to initiate Long-Term Extension OraGrowtH211 Trial, that cash on hand is expected to fund current operations through the read-out of our Phase 2b OraGrowtH210 Trial and completion of the OraGrowtH212 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 OraGrowtH210 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 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 September 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 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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Investor & Media Contact:

Lisa Miller
Lumos Pharma Investor Relations
512-792-5454
ir@lumos-pharma.com

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

	Year Ended December 31,	
	2020	2019
Revenues:		
Licensing and collaboration revenue	\$ 168	\$ —
Total revenues	168	—
Operating expenses:		
Research and development	9,206	5,669
General and administrative	17,265	4,147
Total operating expenses	26,471	9,816
Loss from operations	(26,303)	(9,816)
Other income and expense:		
Other income, net	6,467	37
Interest income	200	74
Other income, net	6,667	111
Net loss before taxes	(19,636)	(9,705)
Income tax benefit	13,973	—
Net loss	(5,663)	(9,705)
Accretion of preferred stock to current redemption value	(651)	(3,040)
Net loss attributable to common shareholders	\$ (6,314)	\$ (12,745)
Net loss per share of common stock		
Basic and diluted	\$ (0.93)	\$ (9.79)
Weighted average number of common shares outstanding		
Basic and diluted	6,777,932	1,302,390

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

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 98,679	\$ 4,952
Prepaid expenses and other current assets	3,506	82
Income tax receivable	115	—
Other receivables	26,149	35
Total current assets	<u>128,449</u>	<u>5,069</u>
Non-current assets:		
Property and equipment, net	335	84
Right-of-use asset	249	373
Total non-current assets	<u>584</u>	<u>457</u>
Total assets	\$ 129,033	\$ 5,526
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 244	\$ 365
Accrued expenses	5,898	709
Current portion of lease liability	319	189
Total current liabilities	<u>6,461</u>	<u>1,263</u>
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	—
Lease liability	—	191
Total long-term liabilities	<u>6,000</u>	<u>191</u>
Total liabilities	12,461	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 December 31, 2020 and 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 December 31, 2020 and 2019, respectively	—	41,631
Stockholders' equity (deficit):		
Undesignated preferred stock, \$— par value: Authorized shares - 5,000,000 at December 31, 2020 and 2019, respectively; issued and outstanding shares —0 at December 31, 2020 and 2019	—	—
Common stock, \$0.01 par value: Authorized shares — 75,000,000 and 36,000,000 at December 31, 2020 and 2019; issued and outstanding 8,305,269 and 1,177,933 at December 31, 2020 and 2019, respectively	83	12
Treasury stock, at cost, 0 and 176,623 shares held as of December 31, 2020 and 2019, respectively	—	—
Additional paid-in capital	182,480	202
Accumulated deficit	(65,991)	(59,677)
Total stockholders' equity (deficit)	<u>116,572</u>	<u>(59,463)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$ 129,033	\$ 5,526



Full Year 2020 Financial Results and Corporate Update

March 9, 2021

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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 meaning of 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 identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among others, statements regarding the potential of an orally administered LUM-201 treatment regimen for PGHD and other indications, the projected cash position and its sufficiency to fund the company's operations through data read-out for the OraGrowth210 Trial in PGHD and completion of the Pharmacokinetic / Pharmacodynamic OraGrowth212 Trial in PGHD; expected initiation of the OraGrowth212 Trial of LUM-201 in PGHD in Q2 2021; the intent to initiate Long-Term Extension OraGrowth211 Trial; impact of regulatory feedback to clinical timelines and costs, results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to execution of clinical trials; plans related to moving additional indications into clinical development; milestones or other economic interests, Lumos Pharma's financial guidance for 2021 and beyond; 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 Lumos Pharma 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 and those risks discussed in "Risk Factors" and elsewhere in Lumos Pharma's Annual Report on Form 10-K for the year ended December 31, 2019, Form 10-Q for the quarter ended September 30, 2020, and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this presentation represent Lumos Pharma's views as of the date of this presentation. Lumos Pharma anticipates that subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing Lumos Pharma's views as of any date subsequent to the date of this presentation. 3/9/2021



Agenda

Welcome

- Lisa Miller, Director of Investor Relations

Introduction & Corporate Update

- Rick Hawkins, CEO

Review of LUM-201 and PGHD

- John McKew, PhD, COO & CSO

Clinical Development Plan

- Eugene Kennedy, MD, Outgoing CMO

Full Year 2020 Financial Results

- Carl Langren, CFO

Overview of Company

Late-stage Rare Disease Asset

Novel therapeutic asset, LUM-201, with validating Phase 2b OraGrowthH210 Trial in Pediatric Growth Hormone Deficiency (PGHD)

Sizable Target Market

Initial indication targeted over \$1B*, with potential to disrupt current treatment regimen for significant subset of patients across multiple indications

Experienced Management

Experienced management team with ability to expand pipeline through addition of other rare disease assets

Solid Cash Position

Cash balance of \$98.7 million at end of Q4 2020 expected to support current operations through OraGrowthH210 Trial read-out anticipated mid-2022

Pipeline Expansion

Final PRV proceeds received January 2021 plus current cash balance also expected to contribute to expansion of the company's portfolio of rare disease assets

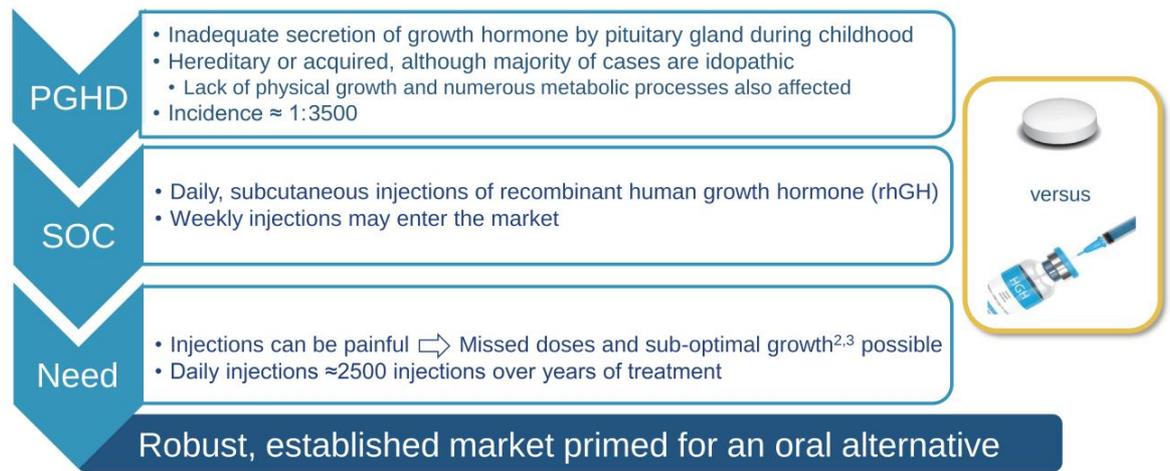
Clinical Development Highlights

- LUM-201 Trials in PGHD
 - Phase 2b OraGrowthH210 Trial initiated Q4 2020
 - PK/PD OraGrowthH212 Trial to be initiated shortly
 - Long-term Extension OraGrowthH211 Trial introduced
- LUM-201 Opportunity Beyond PGHD
 - Potential to evaluate LUM-201 in other GHD indications treated by rhGH
- Data Publications and Presentations Supportive of LUM-201 Potential in PGHD
 - Two peer-reviewed publications in the Journal of Endocrine Society, Feb 2021
 - Data to be presented at ENDO 2021, March 2021

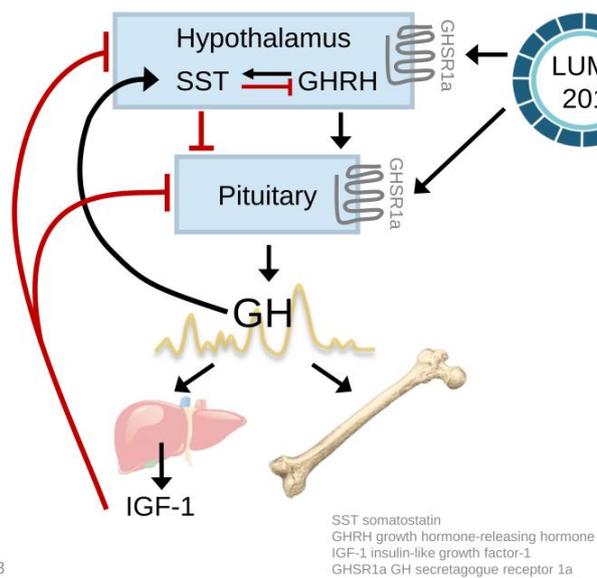
Corporate Update

- Final tranche of \$26 million in proceeds from PRV sale received in January 2021
- PRV proceeds represent non-dilutive funds available for pipeline expansion
- Continue pursuit of additional rare disease assets to broaden portfolio

PGHD and Standard of Care



LUM-201 Mechanism of Action



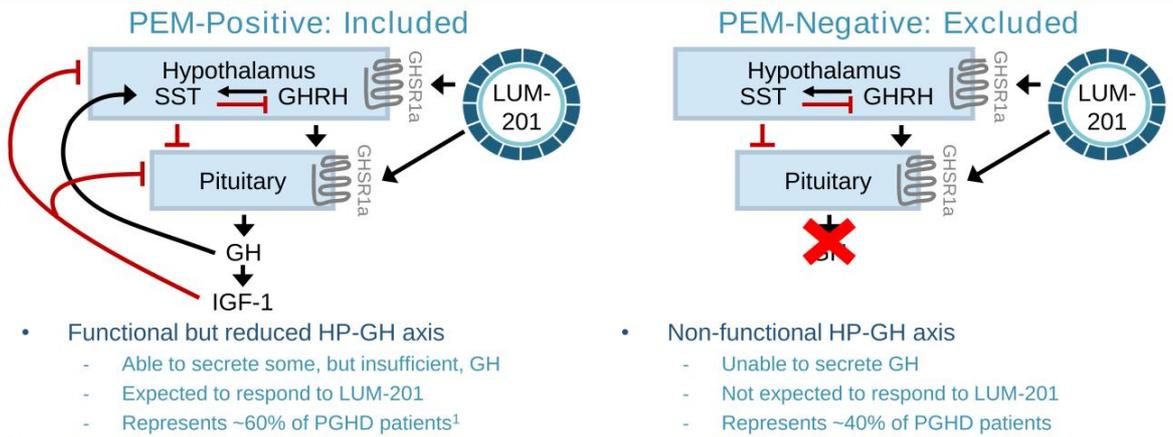
- Oral LUM-201 is a growth hormone (GH) secretagogue
- Acts as an agonist of GH Secretagogue Receptor (GHSR1a) to stimulate GH release¹
- LUM-201 has been observed to increase the amplitude of endogenous pulsatile GH secretion^{2,3}
- LUM-201's stimulatory effect is regulated by GH/IGF-1 feedback

1 Howard 1996 Science

2 Nass 2008 Ann Intern Med

3 Chapman 1997 J Clin Endocrinol Metab

Targeted PGHD Population



Predictive Enrichment Markers (PEMs): GH response to single LUM-201 dose and baseline IGF-1 have potential to distinguish these populations

HP-GH hypothalamic-pituitary-growth hormone

¹ Blum, et al, Corroboration of Height Velocity Prediction Markers for rhGH with an Oral GH Secretagogue Treatment with Children with GHD, Journal of Endocrine Society, Feb 2021. bvab029, <https://doi.org/10.1210/jeendo/bvab029>

Journal Publications and ENDO 2021 Presentation

- Journal of the Endocrine Society Publications, February 2021
 - Development of a Predictive Enrichment Marker for Oral GH Secretagogue LUM-201 in Children with Growth Hormone Deficiency, by Bright, G., et al; bvab029, <https://doi.org/10.1210/jendso/bvab029>
 - Corroboration Between Predictive Enrichment Markers for Height Velocity to rhGH and an Oral GH Secretagogue Treatment in Children with Moderate GHD, by Blum, W., et al; bvab030, <https://doi.org/10.1210/jendso/bvab030>
- ENDO 2021 Poster to be Presented, March 2021
 - LUM-201 Elicits Greater GH Response than Standard GH Secretagogues in Pediatric Growth Hormone Deficiency, by Bright, G., et al; (Abstract 7102)

OraGrowthH210 Trial in PGHD: Clinical Development Outline

Main Objectives for OraGrowth210 Trial:

- Prospectively confirm utility of PEM strategy
- Confirm repeatability of PEM classification
- Determine optimal dose for Phase 3 trial

OraGrowthH210 Trial Sites:

- 40-50 trial sites US & International
- Academic centers & private clinics

OraGrowthH210 Trial Read-Out:

- Anticipated mid-2022

OraGrowthH210

TRIAL

80 randomized PEM Positive PGHD patients
Treatment naive, age matched cohorts,
6-month dosing

20- LUM-201:
0.8 mg/kg/day

20- LUM-201:
1.6 mg/kg/day

20- LUM-201:
3.2 mg/kg/day

20
Daily rhGH
treatment arm

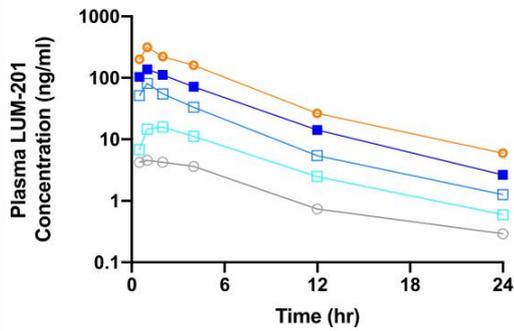
Primary outcome measure: Annualized Height Velocity (AHV)
Anticipate OraGrowthH210 Trial data read-out mid-2022

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

PK/PD Response Supports Proposed Doses in PGHD

Pharmacokinetics

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

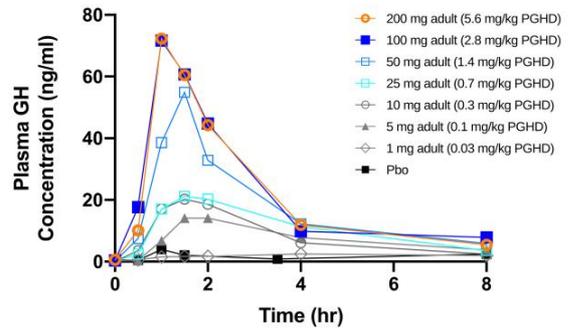


12

Merck Study 001 in healthy adult subjects

Pharmacodynamics

- PD plateau possible ≥ 2.8 mg/kg PGHD dose equivalent*



*Dose equivalence is based on AUC

lumos
PHARMA

OraGrowthH212 Trial: Pharmacokinetic / Pharmacodynamic Trial in PGHD

Purpose of OraGrowthH212 Trial:

- Further explore LUM-201's mechanism of amplification of natural pulsatile secretion of growth hormone
- To expand data package in support of future regulatory filings

OraGrowthH212 Trial Site:

- San Borja Arriaran Hospital, Santiago, Chile

OraGrowthH212 Trial Timeline:

- Anticipated initiation in Q2 2021
- To run concurrent with OraGrowthH210 Trial

OraGrowthH212

TRIAL

24 PEM Positive PGHD patients, Open-label study
Treatment naive, 6-month dosing

12- LUM-201:
1.6 mg/kg/day

12- LUM-201:
3.2 mg/kg/day

Assess LUM-201 effect on endogenous GH pulsatility
Evaluate pharmacokinetics / pharmacodynamics
Q10 minute sampling for 12 hours

Generate additional data to support future regulatory filings

LUM-201 Program Pipeline

	Pre-Clinical	Phase 1	Phase 2	Phase 3	Status
LUM-201 (lbutamoren) in PGHD*			OraGrowthH210 TRIAL		Ongoing Phase 2b trial with data read-out expected mid-2022
			OraGrowthH211 TRIAL		Long-term extension study for OraGrowthH210, OraGrowthH212, and future OraGrowth Trials
			OraGrowthH212 TRIAL		Pharmacokinetic/Pharmacodynamic (PK/PD) trial expected to commence in Q2 2021

Company plans to target other indications for LUM-201 beyond PGHD and pursue acquisitions and collaborations to expand pipeline beyond LUM-201

Secure Cash Position

Metric	Position
Cash balance December 31, 2020	\$98.7 million ¹
Additional non-dilutive resources	Final tranche of \$26 million proceeds from PRV sale received in January 2021
Projected cash use per quarter through 2021	~ \$8 to \$9 million
Shares outstanding as of December 31, 2020	~ 8.3 million

Cash balance plus additional PRV proceeds to support current operations through OraGrowthH210 Trial read-out, OraGrowthH212 Trial completion, and contribute to pipeline expansion

Lumos Pharma: Summary of Investment Thesis



- Lead program, LUM-201, with potential to be the first oral growth hormone secretagogue therapy for PGHD
- Opportunity to disrupt established and sizable injectable market in PGHD and other indications
- Management team with extensive experience in the clinical advancement of rare disease therapeutics
- Strong cash position with additional funds from PRV sale to support current operations through Phase 2b OraGrowth210 Trial read-out mid-2022 and contribute to pipeline expansion

Potential to significantly increase shareholder value

