

**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**

May 10, 2022
Date of Report (date of earliest event reported)

LUMOS PHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

001-35342
(Commission File Number)

42-1491350
(I.R.S. Employer Identification No.)

**4200 Marathon Blvd., Suite 200
Austin, Texas 78756
(Address of Principal Executive Offices)
(512) 215-2630
Registrant's telephone number, including area code**

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). Emerging growth company

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 May 10, 2022, Lumos Pharma, Inc., a Delaware corporation (the "Company"), issued a press release providing an operational update and reporting results for the first quarter ended March 31, 2022 ("Press Release").

A copy of the Press Release and the First Quarter 2022 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated May 10, 2022, entitled " Lumos Pharma Reports First Quarter 2022 Financial Results and Clinical Development Updates. "
99.2	First Quarter 2022 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: May 10, 2022

LUMOS PHARMA, INC.,
a Delaware corporation

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



FOR IMMEDIATE RELEASE

Lumos Pharma Reports First Quarter 2022 Financial Results and Clinical Development Updates

--Phase 2 OraGrowthH210 Trial Reached 50% Randomization Milestone – Interim Data from Phase 2 and PK/PD OraGrowthH Trials Anticipated by End of 2022--

--FDA Permits Treatment with LUM-201 Beyond 12 Months and Lifts Partial Clinical Hold--

--Clinical Collaboration Initiated with Massachusetts General Hospital for Evaluation of LUM-201 in Nonalcoholic Fatty Liver Disease (NAFLD) in Phase 2 Pilot Trial--

AUSTIN, TX, May 10, 2022 - Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, today announced financial results for the quarter ended March 31, 2022 and clinical development updates.

“To date, 2022 has been a productive period for Lumos, with encouraging enrollment trends in both of our OraGrowthH210 and OraGrowthH212 trials evaluating orally administered LUM-201 in pediatric growth hormone disease (PGHD) and our announcement of planned interim data analyses by the end of this year,” said Rick Hawkins, Chairman and CEO of Lumos Pharma. “Other notable events included a journal publication of a peer-reviewed article supporting LUM-201 as a potent GH secretagogue, and the removal of partial clinical hold for treatment past 12 months. With momentum building in our LUM-201 program for PGHD, we are also honored to collaborate with Mass General on an investigator-initiated trial evaluating LUM-201 in NAFLD. We continue to execute on our clinical programs and look forward to interim data from our OraGrowthH Trials later this year.”

Recent Highlights

- **Phase 2 OraGrowthH210 Trial exceeds 50% randomization – Interim analyses for OraGrowthH210 and PK/PD OraGrowthH212 Trials by end of 2022.** OraGrowthH210 has now exceeded the 50% randomization milestone, and subject enrollment in both the OraGrowthH210 and OraGrowthH212 Trials is progressing sufficiently for us to confirm our plan to conduct interim analyses of data from both trials by the end of 2022. We believe the interim data should provide an early indication of efficacy and safety of oral LUM-201 versus standard of care daily rhGH injections in PGHD. We continue to anticipate primary outcome data on 80 subjects from our OraGrowthH210 Trial in the second half of 2023.
- **FDA lifts partial clinical hold on treatment beyond 12 months after review of preliminary data from OraGrowthH trials.** In July 2021, we announced that the U.S. Food & Drug Administration (FDA) had restricted treatment with LUM-201 to no more than 12 months. Based on a review of preliminary safety and efficacy data from both OraGrowthH trials in progress the FDA has lifted the partial hold and will now permit treatment with LUM-201 beyond twelve months. As a result, the OraGrowthH210 Trial will be extended to 24 months to allow subjects to continue LUM-201 therapy uninterrupted. Additionally, we plan to extend the duration of the OraGrowthH212 Trial.
- **Peer-reviewed journal publication demonstrates LUM-201’s potency as GH secretagogue.** A peer-reviewed article illustrating LUM-201’s greater potency over standard growth hormone secretagogues was

published March 30, 2022, in the journal, *Hormone Research in Paediatrics*. The article, co-authored by George Bright, MD and Michael Thorner, MB, BS, entitled “A GH Secretagogue Receptor Agonist (LUM-201) Elicits Greater GH Responses than Standard GH Secretagogues in Subjects of a Pediatric GH Deficiency Trial,” further supports prior data suggesting LUM-201’s therapeutic potential when administered to pediatric subjects with idiopathic growth hormone deficiency.

- **Lumos Pharma collaborates with Massachusetts General to evaluate LUM-201 in NAFLD.** The Company entered into a clinical collaboration with Dr. Laura Dichtel and Massachusetts General Hospital to explore the potential of LUM-201 in Nonalcoholic Fatty Liver Disease (NAFLD) in an investigator-initiated pilot study. While we remain focused on our core LUM-201 program in PGHD, the Company is pleased to support Mass General’s exploration of LUM-201’s potential in this indication, a condition estimated to be prevalent in approximately 25% of adults worldwide. NAFLD can often advance to the more serious liver disease non-alcoholic steatohepatitis (NASH) with fibrosis, and NASH-associated liver failure is one of the leading causes of liver transplants in the United States.

About Lumos Pharma’s Clinical Trials

Phase 2 OraGrowthH210 Trial of Oral LUM-201 in PGHD

The OraGrowthH210 Trial is a multi-site, global trial evaluating orally administered LUM-201 at three dose levels (0.8, 1.6, 3.2 mg/kg/day) against a standard dose of injectable rhGH in approximately 80 subjects diagnosed with idiopathic (moderate) PGHD, which is less severe than organic PGHD. The objective of this trial is to identify the optimal dose of LUM-201 to be used in a Phase 3 registration trial, based on annualized height velocity from a 6-month dataset, and to prospectively confirm the preliminary validation of our Predictive Enrichment Marker (PEM) strategy. The interim analysis will evaluate the safety and annualized height velocity of the three dose levels of LUM-201 against a standard dose of injectable recombinant human growth hormone (rhGH) in a minimum of 40 subjects at six months on therapy. The complete set of 6-month, primary outcome data for 80 patients is anticipated in the second half of 2023. Subjects will be dosed for a total of 24 months.

OraGrowthH212 Trial Evaluating PK/PD and Pulsatility of Oral LUM-201 in PGHD

The OraGrowthH212 Trial is a single site, open-label trial evaluating the pharmacokinetic (PK) and pharmacodynamic (PD) effects of oral LUM-201 in up to 24 PGHD subjects at two dose levels, 1.6 and 3.2 mg/kg/day. The objective of the OraGrowthH212 Trial is to confirm prior clinical data demonstrating the amplified pulsatile release of endogenous growth hormone from LUM-201 therapy differentially contributes to its efficacy in PGHD. The primary endpoint for this trial is six months of PK/PD and height velocity data in up to 24 subjects. Subjects will be dosed for a total of 12 months, with a plan to extend the duration of the trial. Interim data on a minimum of 10 subjects is anticipated by the end of 2022.

Switch Study, OraGrowthH213 Trial, Evaluating LUM-201 in OraGrowthH210 Subjects Previously on rhGH

The OraGrowthH213 Trial is an open-label, multi-center, Phase 2 study evaluating the growth effects and safety of LUM-201 following 12 months of daily rhGH in up to 20 idiopathic PGHD patients who have completed the OraGrowthH210 Trial. Subjects will be administered LUM-201 at a dose level of 3.2 mg/kg/day for up to 12 months.

Lumos Pharma Collaboration with Massachusetts General Hospital Evaluating LUM-201 in NAFLD

Lumos Pharma has entered a collaboration with Massachusetts General Hospital (MGH) to evaluate LUM-201 in patients with nonalcoholic fatty liver disease (NAFLD). GH is a critical stimulator of lipolysis, and preclinical data suggest that amplifying GH secretion has the potential to reduce hepatic steatosis and prevent NAFLD progression. Interestingly, enhancing the natural pulsatile release of GH has been shown clinically in short-term studies to be more efficacious in inducing lipolysis than continuous infusions of GH. This MGH investigator-initiated trial is a single-site, 6-month, open-label pilot study of daily oral LUM-201 in adults with NAFLD. The trial will evaluate a dose of 25 mg/day of LUM-201 in 10 subjects with NAFLD and relative IGF-1 deficiency. The primary endpoints

will be to determine the reduction in liver lipid content, inflammation, and potentially fibrosis in these subjects administered LUM-201 compared to historical placebo-treated controls.

Financial Results for the Quarter Ended March 31, 2022

- Cash Position – Lumos Pharma ended the quarter on March 31, 2022 with cash and cash equivalents totaling \$86.8 million compared to \$94.8 million on December 31, 2021. The Company expects an average cash use of approximately \$8.5 to \$9.5 million per quarter through 2022. Cash on hand as of March 31, 2022 is expected to support operations through the primary outcome data readout from the OraGrowthH210 Trial anticipated in the second half of 2023 and the OraGrowthH212 Trial.
- R&D Expenses – Research and development expenses were \$4.2 million for the quarter ended March 31, 2022, a decrease compared to \$4.7 million for the same period in 2021, primarily due to decreases of \$0.5 million in personnel-related expenses, \$0.3 million in stock compensation expenses and \$0.1 million in legal and consulting expenses, offset by an increase of \$0.5 million in clinical trial and contract manufacturing expenses.
- G&A Expenses – General and administrative expenses were \$3.6 million for the quarter ended March 31, 2022, a decrease compared to \$4.0 million for the same period in 2021, primarily due to decreases of \$0.3 million in legal and consulting expenses, \$0.2 million in stock compensation expenses, and \$0.1 million in depreciation expenses, offset by increases of \$0.1 million in licensing expenses and \$0.2 million in other expenses.
- Net Loss – The net loss for the quarter ended March 31, 2022 was \$7.7 million compared to net loss of \$8.6 million for the same period in 2021.
- Lumos Pharma ended the first quarter 2022 with 8,358,625 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/fz7qwz46>. 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 9647959. 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 OraGrowthH210 Trial, a PK/PD trial, the OraGrowthH212 Trial, and a switch trial, the OraGrowthH213 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 progress in our clinical efforts including comments concerning screening and enrollment for our trials, momentum building in our LUM-201 program for PGHD, anticipated timing of interim analyses of trials, our belief that the interim data should provide an early indication of efficacy and safety of oral LUM-201 versus standard of care daily rhGH injections in PGHD, LUM-201's therapeutic potential when administered to pediatric subjects with idiopathic growth hormone deficiency, expecting the primary outcome data readout for our trials, 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, cash use rate and sufficiency of capital resources to fund our operating requirements through the primary outcome data readout from the 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, 2021, 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.

###

Investor & Media Contact:

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

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

	Three Months Ended March 31,	
	2022	2021
Revenues:		
Royalty revenue	111	—
Total revenues	111	—
Operating expenses:		
Research and development	4,221	4,660
General and administrative	3,621	3,957
Total operating expenses	7,842	8,617
Loss from operations	(7,731)	(8,617)
Other income and expense:		
Other income, net	6	20
Interest income	5	3
Interest expense	—	(37)
Other (expense) income, net	11	(14)
Net loss	<u>\$ (7,720)</u>	<u>\$ (8,631)</u>
Net loss per share:		
Basic and diluted	\$ (0.92)	\$ (1.04)
Weighted average number of common shares outstanding:		
Basic and diluted	8,357,969	8,316,888

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 86,758	\$ 94,809
Prepaid expenses and other current assets	5,753	4,740
Income tax receivable	134	128
Total current assets	<u>92,645</u>	<u>99,677</u>
Non-current assets:		
Property and equipment, net	69	79
Right-of-use asset	476	556
Total non-current assets	<u>545</u>	<u>635</u>
Total assets	<u>\$ 93,190</u>	<u>\$ 100,312</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,799	\$ 612
Accrued expenses	3,098	4,166
Current portion of lease liability	345	352
Total current liabilities	<u>5,242</u>	<u>5,130</u>
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	131	205
Total long-term liabilities	<u>6,131</u>	<u>6,205</u>
Total liabilities	<u>11,373</u>	<u>11,335</u>
Commitments and contingencies:		
Stockholders' equity:		
Undesignated preferred stock, \$0.01 par value: Authorized shares - 5,000,000 at March 31, 2022 and December 31, 2021; issued and outstanding shares - 0 at March 31, 2022 and December 31, 2021	\$ —	\$ —
Common stock, \$0.01 par value: Authorized shares - 75,000,000 at March 31, 2022 and December 31, 2021; issued 8,368,521 and 8,366,819 at March 31, 2022 and December 31, 2021, respectively and outstanding shares - 8,358,625 and 8,357,391 at March 31, 2022 and December 31, 2021, respectively	\$ 83	\$ 83
Treasury stock, at cost, 9,896 and 9,428 shares at March 31, 2022 and December 31, 2021, respectively	\$ (119)	\$ (114)
Additional paid-in capital	\$ 185,994	\$ 185,429
Accumulated deficit	\$ (104,141)	\$ (96,421)
Total stockholders' equity	<u>81,817</u>	<u>88,977</u>
Total liabilities and stockholders' equity	<u>\$ 93,190</u>	<u>\$ 100,312</u>



lumos
PHARMA



**First Quarter 2022
Financial Results &
Clinical Update**

May 10, 2022

Forward Looking Statements

This presentation contains forward-looking statements of Lumos Pharma, Inc. that involve substantial risks and uncertainties. All such statements contained in this presentation are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, a law that 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 progress in our clinical efforts including comments concerning screening and enrollment for our trials, momentum building in our LUM-201 program for PGHD, anticipated timing of interim analyses of trials, our belief that the interim data should provide an early indication of efficacy and safety of oral LUM-201 versus standard of care daily rhGH injections in PGHD, LUM-201's therapeutic potential when administered to pediatric subjects with idiopathic growth hormone deficiency, that the interim sample size should be adequate to provide an initial indication of LUM 201's impact, expecting the primary outcome data readout for our trials, the potential to expand our LUM-201 platform into other indications, future financial performance, results of operations, cash position, cash use rate and sufficiency of our cash resources to fund our operating requirements through the primary outcome data readout from the OraGrowthH210 and OraGrowthH212 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. In addition to other considerations referenced in this paragraph, the recent conflict between Ukraine and Russia has increased the uncertainty in that region and may impact our business in the future. Our forward-looking statements are neither historical facts nor assurances of future performance. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make due to a number of important factors, including the effects of pandemics, other widespread health problems or the Ukraine-Russia conflict, the outcome of our future interactions with regulatory authorities, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, 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 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. 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, 2021, 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 presentation. [8-10-2022](#)

Agenda

Welcome

- Lisa Miller, *Senior Director of Investor Relations*

Introduction & Clinical Development Update

- Rick Hawkins, *Chief Executive Officer & Chairman*

Review of MGH Trial Evaluating LUM-201 in NAFLD

- John McKew, PhD, *President & Chief Scientific Officer*

Brief Remarks on Addition to Management Team

- David B. Karpf, MD, *Chief Medical Officer*

Financial Results

- Lori Lawley, *Chief Financial Officer*

~ Enrollment in OraGrowthH210 Trial exceeds 50% ~

Interim Analysis for Phase 2 OraGrowthH210 Trial

- Interim analysis of data from 40 subjects at 6 months on therapy
- 3 dose levels of oral LUM-201 vs standard dose of rhGH
- Annualized height velocity (AHV) and safety data to be reported
- Interim data readout by end of 2022

Interim Analysis for PK/PD OraGrowthH212 Trial

- Interim analysis of data from 10 subjects at 6 months on therapy
- 2 highest dose levels of oral LUM-201
- Annualized height velocity (AHV) and safety data to be reported
- Interim data readout by end of 2022

OraGrowthH210 Trial: Phase 2 Trial in PGHD

OraGrowthH210 TRIAL

- n = 80
- PEM(+) PGHD subjects
- Inclusion: stim GH \geq 5 ng/ml and baseline IGF-1 $>$ 30 ng/ml
- rhGH treatment naïve
- ~40 trial sites US & International
- Trial opened Q4 2020

R

Interim Data Analysis (n = 40) – at 6 months
 Primary Outcome Data (n = 80) – at 6 months
 Total Study Duration – 24 months

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

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

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

n = 20 Daily rhGH injection

← Screening Randomization Treatment →

Objectives

Primary Endpoint:

- Annualized Height Velocity (AHV)

Goals:

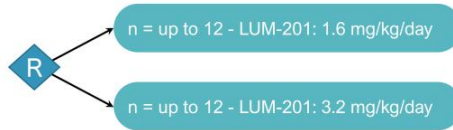
- Prospectively confirm utility of PEM strategy
- Determine optimal dose for Phase 3

Interim AHV and safety data on 40 subjects at 6 months on therapy anticipated by end of 2022
 Primary outcome data for OraGrowthH210 Trial on 80 subjects expected 2H2023

OraGrowthH212 TRIAL

- n = up to 24
- Open-label study
- PGHD patients
- rhGH-treatment naïve
- 12-month dosing
- Single, specialized clinical site
- Q10 minute GH sampling for 12 hours

Interim Data Analysis (n =10) – at 6 months
 Primary Outcome Data (n = up to 24) – at 6 months
 Total Study Duration – 12 months*



Objectives

Primary Endpoints:

- Assess LUM-201 effect on endogenous GH pulsatility and Annualized Height Velocity (AHV)
- Evaluate PK/PD in children

Goals:

- Confirm prior PK/PD data in adults & subset of Merck 020 trial
- Support future regulatory filings & commercialization

Interim AHV and safety data on 10 subjects anticipated by end of 2022

Other Updates

FDA permits LUM-201 treatment beyond 12 months

- After review of unblinded LUM-201 data from OraGrowth Trials, FDA lifts partial clinical hold
- OraGrowth210 and OraGrowth212 Trials extended beyond 12 months
- Primary outcome data for OraGrowth210 & OraGrowth212 Trials at 6-months on treatment

Peer-reviewed analysis of prior LUM-201 data published in journal

- Peer-reviewed article, *LUM-201 Elicits Greater GH Response than Standard GH Secretagogues in Pediatric Growth Hormone Deficiency*, published online in journal, *Hormone Research in Paediatrics*, March 2022

MGH Initiated Phase 2 Pilot Trial

- n = 10
- Adult NAFLD subjects with relative GH/IGF-1 deficiency
- Open-label
- Single-site pilot study
- 6-month dosing

Study Duration – 6 months

n = 10 – LUM-201 at dose level of 25 mg/day

Objectives

Primary Objective:

- Determine changes in intra-hepatic lipid content, inflammation, and potentially fibrosis resulting from LUM-201 induced GH augmentation compared to historical placebo-treated controls

Massachusetts General Hospital (MGH) initiated pilot study of oral LUM-201 in NAFLD approved by FDA

Lumos Pharma Expands Leadership Team

Pisit Pitukcheewanont, MD – renowned pediatric endocrinologist

- Vice President of Global Clinical Development and Medical Affairs for Lumos Pharma
- Professor of Clinical Pediatrics at the Children’s Hospital of Los Angeles, Keck School of Medicine of the University of Southern California; on staff since 1998
- Former president of the Human Growth Foundation
- Authored over 70 publications
- Previously, Vice President of Medical Affairs and Vice President, Global Medical Ambassador and Medical Education for Ascendis Pharma

Secure Cash Position

Metric	Position
Cash balance March 31, 2022	\$86.8 million
Cash use through 2022	\$8.5 to \$9.5 million per quarter
Strong financial position	Cash runway through primary outcome data for OraGrowthH210 and OraGrowthH212 Trials
Shares outstanding as of March 31, 2022	8,358,625

Cash balance to support current operations through primary outcome data readouts for OraGrowthH210 and OraGrowthH212 Trials

Investment Highlights

<p>Novel Oral Rare Disease Asset</p>	<ul style="list-style-type: none"> Novel oral therapeutic asset, LUM-201, for growth hormone deficiency (GHD) disorders Prior data support potential efficacy and safety of LUM-201 across multiple indications Potential to disrupt significant subset of sizable injectable market for GHD 	
<p>Pipeline in a Product</p>	<ul style="list-style-type: none"> Worldwide market for GHD disorders is \$3.4 billion* Market for initial oral LUM-201 indication, PGHD, is \$1.2 billion* 	
<p>Late-stage Trials in PGHD</p>	<ul style="list-style-type: none"> OraGrowthH210 Trial (Phase 2): Interim data by year-end 2022 Primary data 2H2023 OraGrowthH212 Trial (PK/PD): Interim data by year-end 2022 OraGrowthH213 Trial (Switch): Initiated 	
<p>Solid Financial Position</p>	<ul style="list-style-type: none"> Cash balance of \$86.8 million at close of Q1 2022 Cash runway through primary outcome data for OraGrowthH210 & OraGrowthH212 Trials 	

PGHD = Pediatric Growth Hormone Deficiency

* USA, Germany, France, Italy, Spain, UK, Japan (Grandview Research, Growth Hormone Market Forecast, 2019)

