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

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

LUMOS PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35342**	**42-1491350**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(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.

Item 2.02. Results of Operations and Financial Condition.

On March 10, 2022, Lumos Pharma, Inc., a Delaware corporation (the “Company”), issued a press release providing financial results for the year ended December 31, 2021 (the "Press Release").

A copy of the Press Release and the Year End 2021 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 March 10, 2022, entitled "Lumos Pharma Reports Year 2021 Financial Results and Announces Plan to Perform Interim Analyses of OraGrowtH Trials"
99.2	Year End 2021 Financial Results Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 10, 2022

LUMOS PHARMA, INC.,
a Delaware corporation

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

Lumos Pharma Reports Full Year 2021 Financial Results and Announces Plan to Perform Interim Analyses of OraGrowtH Trials

Data from interim analyses of Phase 2 OraGrowtH210 Trial and PK/PD OraGrowtH212 Trial evaluating oral LUM-201 in PGHD anticipated by the end of 2022

AUSTIN, TX, March 10, 2022 - 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, 2021, announced plans to conduct interim analyses of its OraGrowtH210 and OraGrowtH212 Trials, and provided an update on clinical activities and financial guidance for 2022.

“We are excited to announce that we plan to conduct interim analyses on two of our OraGrowtH Trials evaluating orally administered LUM-201 in PGHD,” commented Rick Hawkins, Chairman and CEO of Lumos Pharma. “With continued positive trends in screening and enrollment, we wanted to provide interim clinical and safety data from our OraGrowtH210 and OraGrowtH212 Trials in order to offer an early look at the potential for LUM-201 to treat idiopathic PGHD patients who would otherwise face years of burdensome injections as their only course of treatment. Based upon prior trials of growth hormone in PGHD, we believe these data should be adequate to provide an initial indication of LUM-201’s impact on height velocity compared to growth hormone.”

Clinical and Business Updates

- **Phase 2 OraGrowtH210 Trial of Oral LUM-201 in PGHD – Approaching 50% Enrollment, Interim Analysis Planned**
  - We are approaching the 50% enrollment milestone for the OraGrowtH210 Trial, and as a result we anticipate reporting top line data from an interim analysis by the end of 2022. The interim analysis will evaluate the safety and annualized height velocity at three dose levels of LUM-201 against a standard dose of injectable recombinant human growth hormone (rhGH) in 40 subjects at six months on therapy.
  - The Phase 2 OraGrowtH210 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 PGHD, which is less severe than organic PGHD, when fully enrolled. 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.
  - Due to the ongoing conflict between Ukraine and Russia and the resulting uncertainty in the region, we are unable to enroll patients in Ukraine, and all of our clinical sites in both Ukraine and Russia are suspended until further notice. No patients had been randomized to treatment in the clinical trial at any of our nine sites in Ukraine and Russia. Given the encouraging screening and enrollment trajectory at our other clinical sites, we continue to anticipate the 6-month primary outcome data on all 80 subjects in the second half of 2023. The ongoing conflict may, however, adversely impact our business in the future, and it remains too early to evaluate the potential effects of this crisis.

- **OraGrowthH212 Trial to Evaluate PK/PD and Pulsatility of Oral LUM-201 in PGHD – Interim Analysis Planned**
  - The OraGrowthH212 Trial continues to enroll, with an interim analysis to evaluate the safety and height velocity data anticipated by the end of 2022. Enrollment in the trial is approaching the minimum number of 10 patients for the interim analysis.
  - The OraGrowthH212 Trial is a single site, open-label trial evaluating the pharmacokinetic (PK) and pharmacodynamic (PD) effects of LUM-201 in up to 24 PGHD patients 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 unique to LUM-201 and its potential for this mechanism of action to contribute to efficacy in PGHD. The primary endpoint is six months of PK/PD and height velocity data, with a total of 12 months of height velocity data to be captured.

- **Switch Study, OraGrowthH213 Trial, in PGHD – Initiated**
  - We initiated our OraGrowthH213 Trial, an open-label, multi-center, Phase 2 study evaluating the growth effects and safety of orally administered LUM-201 following 12 months of daily injectable rhGH in up to 20 PGHD subjects 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.

Financial Results for the Year Ended December 31, 2021

- **Cash Position –** Lumos Pharma ended the year on December 31, 2021, with cash and cash equivalents totaling $94.8 million compared to $98.7 million on December 31, 2020. The Company expects an average cash use of approximately $8.5 to $9.5 million per quarter through 2022. Cash on hand as of year-end 2021 is expected to support operations through the primary outcome data readout from our OraGrowthH210 and OraGrowthH212 Trials anticipated in the second half of 2023.
- **R&D Expenses –** Research and development expenses were $16.2 million, an increase of $7.0 million for the year ended December 31, 2021 compared to the same period in 2020, primarily due to increases of $5.5 million in clinical trial and contract manufacturing expenses, $2.0 million in personnel-related expenses and $0.7 million in stock compensation expenses, offset by decreases of $0.3 million in legal and consulting expenses, $0.4 million in operating expenses for supplies, depreciation, and rent, and $0.5 million in other expenses.
- **G&A Expenses –** General and administrative expenses were $15.3 million, a decrease of $1.9 million for the year ended December 31, 2021, as compared to the same period in 2020, primarily due to decreases of $1.9 million in legal and consulting expenses, which were higher in 2020 due to merger-related expenses, $1.1 million in personnel-related expenses, and $0.5 million in operating expenses for rent, supplies, and depreciation, offset by increases of $1.0 million in stock compensation expense and $0.6 million in traveling, licensing, and other expenses.
- **Net Loss –** The net loss for the year ended December 31, 2021 was $30.4 million compared to a net loss of $5.7 million for the same period in 2020.
- Lumos Pharma ended Q4 2021 with 8,357,391 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/r38rwhd6. 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 9248229. 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 OraGrowtH210 Trial, and a PK/PD trial, the OraGrowtH212 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 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 screening and enrollment for both our OraGrowtH210 and OraGrowtH212 Trials progressing well, anticipating interim analyses of OraGrowtH210 and OraGrowtH212 Trials by the end of 2022, 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 OraGrowtH210 Trial in the second half of 2023, the potential to expand our LUM-201 platform into other indications, future financial performance, results of operations, cash usage and cash position and sufficiency of our cash resources to fund our operating requirements through the primary outcome data readout from 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. 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, 2020, 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.

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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,	
	2021	**2020**
Revenues:		
Licensing and collaboration revenue	$ 10	$ 168
Royalty revenue	220	—
Total revenues	230	168
Operating expenses:		
Research and development	16,246	9,206
General and administrative	15,331	17,265
Total operating expenses	31,577	26,471
Loss from operations	(31,347)	(26,303)
Other income and expense:		
Other income, net	269	6,467
Interest income	12	200
Other income, net	281	6,667
Net loss before taxes	(31,066)	(19,636)
Income tax benefit	636	13,973
Net loss	(30,430)	(5,663)
Accretion of preferred stock to current redemption value	—	(651)
Net loss attributable to common shareholders	$ (30,430)	$ (6,314)
Net loss per share of common stock		
Basic and diluted	$ (3.65)	$ (0.93)
Weighted average number of common shares outstanding		
Basic and diluted	8,334,516	6,777,932

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

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 94,809	$ 98,679
Prepaid expenses and other current assets	4,740	3,506
Income tax receivable	128	115
Other receivables	—	26,149
Total current assets	99,677	128,449
Non-current assets:		
Property and equipment, net	79	335
Right-of-use asset	556	249
Total non-current assets	635	584
Total assets	$ 100,312	$ 129,033
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 612	$ 244
Accrued expenses	4,166	5,898
Current portion of lease liability	352	319
Total current liabilities	5,130	6,461
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	205	—
Total long-term liabilities	6,205	6,000
Total liabilities	11,335	12,461
Commitments and contingencies:		
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at December 31, 2021 and 2020, respectively; issued and outstanding shares — 0 at December 31, 2021 and 2020	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at December 31, 2021 and 2020; issued shares 8,366,819 and 8,305,269 at December 31, 2021 and 2020, respectively, and outstanding shares - 8,357,391 and 8,305,269 at December 31, 2021 and 2020, respectively	83	83
Treasury stock, at cost, 9,428 and 0 shares held as of December 31, 2021 and 2020, respectively	(114)	—
Additional paid-in capital	185,429	182,480
Accumulated deficit	(96,421)	(65,991)
Total stockholders' equity	88,977	116,572
Total liabilities and stockholders' equity	$ 100,312	$ 129,033


lumos
PHARMA
Full Year 2021
Financial Results &
Clinical Update
March 10, 2022

Forward Looking Statements

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Agenda

Welcome

- Lisa Miller, *Senior Director of Investor Relations*

Clinical Development Update

- Rick Hawkins, *Chief Executive Officer & Chairman*

Financial Results

- Lori Lawley, *Chief Financial Officer*

Question & Answer Session

- Rick Hawkins, *Chief Executive Officer & Chairman*
- John McKew, PhD, *President & Chief Scientific Officer*
- David B. Karpf, MD, *Chief Medical Officer*
- Lori Lawley, *Chief Financial Officer*

New Plan for Interim Analyses for OraGrowtH210 and OraGrowtH212 Trials

Interim Analysis for Phase 2 OraGrowtH210 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 anticipated by end of 2022

Interim Analysis for PK/PD OraGrowtH212 Trial

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

LUM-201 Program Pipeline

	Study	Pre-Clinical	Phase 1	Phase 2	Phase 3	Status
LUM-201 (Ibutamoren) In PGHD	Phase 2	OraGrowtH210 TRIAL				Ongoing Phase 2 trial: Interim analysis anticipated by year-end 2022 | Primary outcome data 2H2023
	Long-term extension	OraGrowtH211 TRIAL				Proposed long-term extension study for OraGrowtH Trials
	PK/PD trial	OraGrowtH212 TRIAL				PK/PD trial: Interim analysis anticipated by year-end 2022
	Switch trial	OraGrowtH213 TRIAL				Switch trial evaluating LUM-201 in subjects from rhGH arm of OraGrowtH210 Trial: Initiated

Lumos is evaluating additional indications for LUM-201 for Phase 2 studies

- Small for Gestational Age
- Prader-Willi Syndrome
- Turner Syndrome
- Idiopathic Short Stature

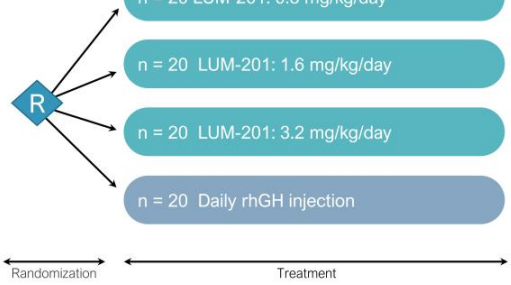
PGHD Pediatric Growth Hormone Deficiency

OraGrowthH210 Trial: Phase 2 Trial in PGHD

OraGrowthH210 TRIAL

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

Interim Data Analysis (n = 40) – at 6 months
Primary Outcome Data (n = 80) – at 6 months
Total Study Duration – 12 months



Screening | Randomization | Treatment

Objectives

Primary Endpoint:
- Annualized Height Velocity (AHV)

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

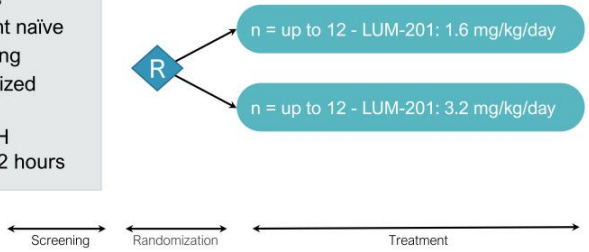
Interim AHV and safety data on 40 subjects at 6 months on therapy anticipated by end of 2022
Primary outcome data for OraGrowthH210 Trial on 80 subjects 2H2023

OraGrowthH212 Trial: Pharmacokinetic / Pharmacodynamic Trial in PGHD

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

OraGrowthH213 Trial: Phase 2 Switch Trial in PGHD

OraGrowthH213 TRIAL

- n = up to 20
- PGHD subjects from rhGH treatment arm of OraGrowthH210 Trial after completion of 12 months on therapy
- Open-label, multi-center switch study
- LUM-201 treatment months 13-24

Total Study Duration – 12 months

n = up to 20 – LUM-201 at dose level of 3.2 mg/kg/day

Objectives

Primary Objectives:

- Assess growth and safety of oral LUM-201 following 12 months of daily injections of rhGH

Switch study initiated

Secure Cash Position

Metric	Position
Cash balance December 31, 2021	$94.8 million
Cash use through 2022	$8.5 to $9.5 million per quarter
Strong financial position	Cash runway through primary outcome data for OraGrowtH210 and OraGrowtH212 Trials
Shares outstanding as of December 31, 2021	8,357,391

Cash balance to support current operations through primary outcome data readouts for OraGrowtH210 and OraGrowtH212 Trials

Investment Highlights

Novel Oral Rare Disease Asset	• 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
Pipeline in a Product	• Worldwide market for GHD disorders is **$3.4 billion*** • Market for initial oral LUM-201 indication, PGHD, is **$1.2 billion***
Late-stage Trials in PGHD	• **OraGrowtH210 Trial** (Phase 2): Interim data by year-end 2022 | Primary data 2H2023 • **OraGrowtH212 Trial** (PK/PD): Interim data by year-end 2022 • **OraGrowtH213 Trial** (Switch): Initiated
Solid Financial Position	• Cash balance of **$94.8 million** at close of Q4 2021 • Cash runway through primary outcome data for OraGrowtH210 & OraGrowtH212 Trials

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