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

November 14, 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.

Section 2 - Financial Information

Item 2.02. Results of Operations and Financial Condition.

On November 14, 2022, Lumos Pharma, Inc., a Delaware corporation (the “Company”), issued a press release providing an operational update and reporting results for the third quarter ended September 30, 2022 ("Press Release").

A copy of the Press Release is attached hereto as Exhibits 99.1, and is incorporated herein by reference.

The information in this Current Report, including Exhibit 99.1 attached hereto is 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 November 14, 2022, entitled "Lumos Pharma Reports Third Quarter 2022 Financial Results and Clinical Development Updates"

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: November 14, 2022

LUMOS PHARMA, INC.,
a Delaware corporation

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

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

-- Interim Data for Potentially the First Oral Medication for PGHD from Phase 2 OraGrowtH210 and PK/PD OraGrowtH212 Trials Met Expectations with an Encouraging Growth Response of 8.6 cm/yr at six months for the LUM-201 Dose of 1.6 mg/kg/day in the OraGrowtH210 Trial which Supports Advanced Planning for Pivotal Phase 3 Trial --

-- OraGrowtH210 Trial is ~80% enrolled and Primary Outcome Readout with all 80 Subjects at six months Anticipated 2H 2023 –

-- First Subject Dosed and Enrollment Ongoing in Massachusetts General Investigator-Initiated Trial evaluating LUM-201 in Non-Alcohol Fatty Liver Disease (NAFLD) --

-- Cash of $73.7 Million at End of Q3 2022 Provides Runway into Second Quarter 2024 --

AUSTIN, TX, November 14, 2022 – Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, today announced that interim results met expectations for its Phase 2 OraGrowtH210 Trial and Phase 2 Pharmacokinetic/Pharmacodynamic (PK/PD) OraGrowtH212 Trial evaluating oral LUM-201 for subjects with moderate (idiopathic) pediatric growth hormone deficiency (PGHD) who screened PEM-positive utilizing Lumos's predictive enrichment marker (PEM) strategy. Lumos also announced its financial results for the quarter ended September 30, 2022.

"With the interim readout from our OraGrowtH210 and OraGrowtH212 trials announced today, we look forward to continuing to advance our clinical program and planning for our pivotal Phase 3 trial for potentially the first oral therapeutic for PGHD," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "In the 1.6 mg/kg/day LUM-201 arm in the OraGrowtH210 study, we observed mean annualized height velocity of 8.6 cm/yr, in line with 8.3 cm/yr expected based on growth on rhGH for moderate PGHD subjects observed in multiple large datasets. We look forward to building on this initial data and expect to report primary outcome results from both OraGrowtH trials in the second half of 2023. Additionally, our collaboration with Mass General on an investigator sponsored trial evaluating LUM-201 in NAFLD continues, and the trial has dosed its first subject and continues to enroll."

Recent Highlights

- **Interim analyses for Phase 2 OraGrowtH210 and PK/PD OraGrowtH212 Trials met expectations.** Interim analysis for Phase 2 OraGrowtH210 Trial demonstrated that the 1.6 mg/kg/day LUM-201 dose produced a mean annualized height velocity (AHV) of 8.6 cm/yr at six months on treatment for moderate (idiopathic) PGHD subjects. This met the expected AHV of 8.3 cm/yr observed for moderate naive-to-treatment PGHD subjects on rhGH at 12 months observed in Eli Lilly's large Phase 4 GeNeSIS[1] dataset and comparable findings from other large historical datasets.[2,3] In addition, interim data from both OraGrowtH210 and OraGrowtH212 Trials demonstrated durability of LUM-201 response out to 12 months. The rhGH control arm produced an AHV of 11.05 cm at six months, an unexpected growth response in this moderate PGHD

population. This higher than anticipated AHV in the rhGH arm was likely due both to the presence of a growth outlier and to imbalances in several baseline characteristics for this arm that are well documented in the published literature as predictors of greater growth response to rhGH. We believe LUM-201 will demonstrate a favorable safety profile as our interim data from both OraGrowtH trials show comparable safety and tolerability to the rhGH subjects in the trials. Interim data from both OraGrowtH trials support the selection of the 1.6 mg/kg/day LUM-201 dose for a pivotal Phase 3 trial. For a link to the Company's conference call and presentation of the data refer to the Company's website at Investor Relations - Events and Presentations.

- **Enrollment for the OraGrowtH210 Trial is now at ~80%.** The primary outcome data on 80 subjects from OraGrowtH210 Trial and up to 24 subjects from our OraGrowtH212 Trial continues to be anticipated in the second half of 2023.

- **Enrollment Initiated in Massachusetts General Investigator-Initiated Trial evaluating LUM-201 in NAFLD.** As previously announced, we 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 sponsored pilot study. Enrollment in the trial has begun, and the first subject has been dosed. While we remain focused on our core LUM-201 program in PGHD, we are 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.

[1] Blum et al JES 2021, [2] Lechuga-Sancho et al JPEM 2009, [3] Ranke et al JCEM 2010,

Financial Results for the Quarter Ended September 30, 2022

- Cash Position – Lumos Pharma ended the quarter on September 30, 2022 with cash and cash equivalents totaling $73.7 million compared to $94.8 million on December 31, 2021. The Company expects cash use of approximately $8.5 to $9.5 million in the fourth quarter of 2022. Cash on hand as of September 30, 2022 is expected to support operations into the second quarter of 2024, inclusive of the primary outcome data readout from OraGrowtH210 and OraGrowtH212 Trials anticipated in the second half of 2023.
- R&D Expenses – Research and development expenses were $4.1 million for the quarter ended September 30, 2022, compared to $4.1 million for the same period in 2021, primarily due to an increase of $0.3 million in personnel-related expenses and $0.1 million in consulting expenses, offset by a decrease of $0.4 million in clinical trial and contract manufacturing expenses.
- G&A Expenses – General and administrative expenses were $3.9 million for the quarter ended September 30, 2022, an increase compared to $3.4 million for the same period in 2021, primarily due to increases of $0.3 million in royalty expenses, $0.2 million in consulting expenses and $0.1 million in travel-related expenses, offset by a decrease of $0.1 million in other miscellaneous expenses.
- Net Loss – The net loss for the quarter ended September 30, 2022 was $7.3 million compared to net loss of $7.5 million for the same period in 2021.
- Lumos Pharma ended the third quarter 2022 with 8,375,271 shares outstanding.

About Lumos Pharma's Clinical Trials

Phase 2 OraGrowtH210 Trial of Oral LUM-201 in PGHD

The 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 (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 demonstrated that LUM-201 in the 1.6 mg/kg/day arm met expectations at six months of treatment with an AHV of 8.6 cm as compared to the AHV of 8.3 cm observed in the PEM-positive moderate naive-to-treatment PGHD subjects for 12 months on rhGH as derived from the large 20-year Phase 4 Eli Lilly GeNeSIS database. The complete set of six-month, primary outcome data for 80 subjects is anticipated in the second half of 2023. Subjects will be treated for up to 24 months.

OraGrowtH212 Trial Evaluating PK/PD and Pulsatility of Oral LUM-201 in PGHD

The OraGrowtH212 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 primary objective of the OraGrowtH212 Trial is to confirm prior clinical data demonstrating the amplified pulsatile release of endogenous growth hormone from LUM-201 therapy, contributes to its efficacy in PGHD. The primary endpoint for this trial is six months of PK/PD (pulsatility) and height velocity data in up to 24 subjects. Subjects will be allowed to remain on treatment until they reach their near-adult height. Primary data readout in up to 24 subjects is anticipated in the second half of 2023.

Switch Study, OraGrowtH213 Trial, Evaluating LUM-201 in OraGrowtH210 Subjects Previously on rhGH

The OraGrowtH213 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 subjects who have completed the OraGrowtH210 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 subjects with nonalcoholic fatty liver disease (NAFLD). GH is a critical stimulator of lipolysis, and shows anti-inflammatory effects, 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 ten subjects with NAFLD and relative IGF-1 deficiency. The primary endpoints will be to determine the reduction in liver lipid content, inflammation, and fibrosis in these subjects administered LUM-201 compared to each subject's baseline.

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, a PK/PD trial, the OraGrowtH212 Trial, and a switch trial, the OraGrowtH213 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 subjects 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 the encouraging growth response in our LUM-201 trials, progress in our clinical efforts including comments concerning screening and enrollment for our trials, 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 and sufficiency of capital resources to fund our operating requirements through the primary outcome data readout from the OraGrowtH210 and OraGrowtH212 Trials, our belief that LUM-201 will demonstrate a favorable safety profile 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 including risks related to the final results of our LUM-201 Trials being different than our interim results, 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 and maintain 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 including information 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 most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2022. 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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Lumos Pharma, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Royalty revenue	497	$ —	$ 1,011	$ —
Licensing and collaboration revenue	—	—	—	10
Total revenues	497	—	1,011	10
Operating expenses:				
Research and development	4,129	4,112	12,995	12,885
General and administrative	3,918	3,385	11,221	11,903
Total operating expenses	8,047	7,497	24,216	24,788
Loss from operations	(7,550)	(7,497)	(23,205)	(24,778)
Other income and expense:				
Other income, net	7	7	19	19
Interest income	292	2	371	7
Interest expense	—	—	—	(37)
Other income (expense), net	299	9	390	(11)
Net loss	$ (7,251)	$ (7,488)	$ (22,815)	$ (24,789)
Net loss per share:				
Basic and diluted	$ (0.86)	$ (0.90)	$ (2.73)	$ (2.97)
Weighted average number of common shares outstanding:				
Basic and diluted	8,388,029	8,357,391	8,371,449	8,333,017

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 73,666	$ 94,809
Prepaid expenses and other current assets	4,998	4,740
Income tax receivable	168	128
Total current assets	78,832	99,677
Non-current assets:		
Property and equipment, net	65	79
Right-of-use asset	312	556
Total non-current assets	377	635
Total assets	$ 79,209	$ 100,312
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 710	$ 612
Accrued expenses	4,479	4,166
Current portion of lease liability	294	352
Total current liabilities	5,483	5,130
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	19	205
Total long-term liabilities	6,019	6,205
Total liabilities	11,502	11,335
Commitments and contingencies		
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at September 30, 2022 and December 31, 2021; issued and outstanding shares - 0 at September 30, 2022 and December 31, 2021	$ —	$ —
Common stock, $0.01 par value: Authorized shares - 75,000,000 at September 30, 2022 and December 31, 2021; issued 8,391,011 and 8,366,819 at September 30, 2022 and December 31, 2021, respectively and outstanding shares - 8,375,271 and 8,357,391 at September 30, 2022 and December 31, 2021, respectively	$ 83	$ 83
Treasury stock, at cost, 15,740 and 9,428 shares at September 30, 2022 and December 31, 2021, respectively	$ (170)	$ (114)
Additional paid-in capital	$ 187,030	$ 185,429
Accumulated deficit	$ (119,236)	$ (96,421)
Total stockholders' equity	67,707	88,977
Total liabilities and stockholders' equity	$ 79,209	$ 100,312