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 7, 2023
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 7, 2023, 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, 2023 ("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 Exhibits 99.1 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 November 7, 2023, entitled "Lumos Pharma Reports Third Quarter 2023 Financial Results, Provides Clinical Update"

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 7, 2023

LUMOS PHARMA, INC.,
a Delaware corporation

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

Lumos Pharma Reports Third Quarter 2023 Financial Results and Clinical Development Updates

-- Phase 2 Data for Potentially the First Oral Therapeutic for PGHD Met All Primary and Secondary Endpoints with Supportive Evidence to Advance to Phase 3 –

-- OraGrowtH210 Trial Results Show LUM-201 Dose of 1.6 mg/kg Achieves AHVs of 8.2 cm/yr at 6 Months and 8.0 cm/yr at 12 Months, Consistent with Historical Growth Rates for Moderate PGHD Population –

-- OraGrowtH212 Data Confirm Unique Pulsatile Mechanism of Action of LUM-201 and Demonstrate Closer to Normal Physiological Growth Hormone Levels and Normalized IGF-1 Levels –

-- Cash of $42.7 Million at End of Q3 2023 Provides Runway through Third Quarter 2024

AUSTIN, TX, November 7, 2023 – Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, today announced that topline results met primary and secondary endpoints for its Phase 2 Dose-Finding OraGrowtH210 Trial and Phase 2 Pharmacokinetic/Pharmacodynamic (PK/PD) OraGrowtH212 Trial evaluating oral LUM-201 for subjects with moderate pediatric growth hormone deficiency (PGHD) who screened PEM-positive utilizing Lumos Pharma's predictive enrichment marker (PEM) strategy. Lumos also announced its financial results for the quarter ended September 30, 2023.

"With the end of Phase 2 readout from our OraGrowtH210 and OraGrowtH212 trials announced today, we are thrilled that these data support advancing our clinical program towards a pivotal Phase 3 trial for potentially the first oral therapeutic for moderate PGHD," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "Data confirm the optimal dose is 1.6 mg/kg/day LUM-201 to advance to Phase 3, and preliminary data show durability out to 24 months of treatment. Additionally, the OraGrowtH212 data reaffirms our confidence in our oral compound's unique mechanism of action, the importance of the natural, pulsatile release of growth hormone, and its impact on restoring growth."

Recent Highlights

- **Phase 2 OraGrowtH210 and PK/PD OraGrowtH212 Trials met all primary and secondary endpoints.** Data from the topline Phase 2 OraGrowtH210 Trial demonstrated that the 1.6 mg/kg/day LUM-201 dose produced a mean annualized height velocity (AHV) of 8.2 cm/yr at six months on treatment for moderate PGHD subjects, in line with historical data in moderate PGHD patients[1,2,3,4]. Additionally, at twelve months on treatment, a durable effect was also observed with LUM-201 achieving AHV of 8.0 cm/yr at the 1.6 mg/kg dose, within the targeted 2 cm/yr margin of the comparator injectable rhGH arm. Data also provided preliminary validation of the PEM strategy, with prespecified primary and secondary outcomes met, de-risking our patient selection for our Phase 3 program. Data from the OraGrowtH212 Trial confirmed that LUM-201's unique pulsatile mechanism produces an increase in the growth rates by restoring growth hormone

secretion and IGF-1 to within normal ranges. The safety profile for LUM-201 remained clean throughout both Phase 2 trials, with no safety concerns identified in either of our Phase 2 trials conducted thus far. For a link to the Company's conference call and presentation of the data refer to the Events & Presentations page in the Investors & Media section of the Company's website.

- **OraGrowtH212 Trial Data Presented at the 2023 annual meeting of the European Society for Paediatric Endocrinology.** An oral presentation of the deconvolution analysis of growth hormone (GH) concentration sampled over 12 hours at baseline and after 6 months of therapy with daily oral LUM-201 illustrated how treatment with LUM-201 increases AHV, total GH secretion, and serum IGF-1 and IGFBP3 for individuals with moderate PGHD. Measured at 6 months compared to baseline, data showed a 60% increase in GH secretion to a level comparable to established values in normal healthy children and a 62% increase in AHV.

- **Independent Panel of Renowned Pediatric Endocrinologists Discussed PGHD and Therapeutic Landscape.** On September 5, 2023, a panel of five pediatric endocrinologists participated in a webinar where they discussed the benefits that the oral therapeutic LUM-201 candidate may provide compared to current injectable therapeutic options.

Upcoming Events

- **Virtual KOL Event Planned.** The Company plans to host a virtual KOL Event on December 6th to discuss topline results from OraGrowtH210 and OraGrowtH212 trials in greater detail and provide updates on clinical and corporate strategy. Management will be joined by the following three esteemed thought leaders in the field of endocrinology:
  - **Andrew Dauber, MD**, Chief of Endocrinology at Children's National Medical Center, Washington, D.C.
  - **Fernando Cassorla, MD**, Chief of Pediatric Endocrinology at the Institute of Maternal and Child Research, University of Chile
  - **Leslie A. Soyka, MD**, Chief of Pediatric Endocrinology, UMass Memorial Medical Center; Associate Professor, UMass Chan Medical School, Worcester, MA

Access information regarding the KOL Event will be provided at a later date.

[1] Blum et al JES 2021, [2] Lechuga-Sancho et al JPEM 2009, [3] Ranke et al JCEM 2010, [4] For all OraGrowtH Trial AHV values, ANCOVA Model Terms: treatment, Age at dose 1, Sex, Baseline HT SDS, Baseline BMI SDS, Baseline IGF-1 SDS, LUM-201 PEM, Baseline BA Delay

Financial Results for the Quarter Ended September 30, 2023

- Cash Position – Lumos Pharma ended the quarter on September 30, 2023 with cash, cash equivalents and short-term investments totaling $42.7 million compared to $67.4 million on December 31, 2022. The Company expects cash use of approximately $9.0 to $10.0 million in the fourth quarter of 2023. Cash on hand as of September 30, 2023 is expected to support operations through the third quarter of 2024, inclusive of the activities related to planning and initiation of a pivotal Phase 3 clinical trial.
- R&D Expenses – Research and development expenses were $5.0 million for the quarter ended September 30, 2023, compared to $4.1 million for the same period in 2022, primarily due to an increase of $0.9 million in clinical trial expenses and $0.2 million in consulting expenses, offset by a decrease of $0.2 million in personnel-related expenses.

- G&A Expenses – General and administrative expenses were $3.9 million for the quarter ended September 30, 2023, compared to $3.9 million for the same period in 2022, primarily due to an increase of $0.3 million in personnel-related expenses offset by a $0.3 million decrease in royalty expense.
- Net Loss – The net loss for the quarter ended September 30, 2023 was $8.3 million compared to a net loss of $7.3 million for the same period in 2022.
- Lumos Pharma ended the third quarter 2023 with 7,914,582 shares outstanding.

About Lumos Pharma's Clinical Trials

Phase 2 OraGrowtH210 Trial Design

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) compared to daily injectable recombinant human growth hormone (rhGH) 34 µg/kg/day in 82 subjects diagnosed with moderate PGHD. The trial population was enriched for subjects responsive to LUM-201 during screening by applying the specific PEM cutoffs of a baseline IGF-1 value > 30 ng/ml and a peak growth hormone value of ≥ 5 ng/ml after administering a single dose of 0.8 mg/kg of LUM-201 to treatment-naïve PGHD patients. The study was not designed to evaluate efficacy and demonstrate non-inferiority to daily GH.

OraGrowtH212 Trial Design

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 treatment-naïve PGHD subjects at two dose levels, 1.6 and 3.2 mg/kg/day. Every subject in the OraGrowtH212 Trial was PEM-positive and, therefore, enriched for responsiveness to LUM-201.

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

The OraGrowtH213 Trial is an open-label, multi-center, Phase 2 trial 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.

About Lumos Pharma

Lumos Pharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of therapeutics for rare diseases. The Company was founded and is led by a management team with longstanding experience in rare disease drug development. Lumos Pharma's lead therapeutic candidate, LUM-201, is a novel, oral growth hormone (GH) secretagogue, seeking to transform the ~$3.4B global GH market from injectable to oral therapy. LUM-201 is currently being evaluated in multiple Phase 2 clinical studies in Pediatric Growth Hormone Deficiency (PGHD) and 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 our Phase 2 data providing supportive evidence to advance oral LUM-201 to Phase 3, the potential for LUM-201 to be the first oral therapeutic for PGHD, data from the OraGrowtH210 Trial supporting the 1.6 mg/kg dose for LUM-201 as the optimal dose for a Phase 3 trial, our confidence in our oral compound’s unique mechanism of action, the importance of the natural, pulsatile release of growth hormone, and its impact on restoring growth, our confidence in our oral compound’s unique mechanism of action, the importance of the natural, pulsatile release of growth hormone, and its impact on restoring growth, de-risking our patient selection for our Phase 3 program, expecting cash use of approximately $9.0 to $10.0 million in the fourth quarter of 2023, that cash on hand as of September 30, 2023 is expected to support operations through the third quarter of 2024, future financial performance, results of operations, our cash position and sufficiency of capital resources to fund our operating requirements through future clinical 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 including risks related to the continued analysis of data from our LUM-201 Trials, the timing and outcome of our future interactions with regulatory authorities including our end of Phase 2 meeting with the FDA, the timing and ability of Lumos to raise additional equity capital as needed to fund our Phase 3 Trial, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to structure our Phase 3 trial in an effective and timely manner, the ability to successfully develop our product candidate, the effects of pandemics, other widespread health problems or military conflicts including the Ukraine-Russia conflict and the Middle East conflict 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 Quarterly Report on Form 10-Q for the period ended June 30, 2023, as well as other reports filed with the SEC including our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. 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.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Royalty revenue	$ 7	$ 497	$ 1,225	$ 1,011
Total revenues	7	497	1,225	1,011
Operating expenses:				
Research and development	5,046	4,129	15,439	12,995
General and administrative	3,893	3,918	12,396	11,221
Total operating expenses	8,939	8,047	27,835	24,216
Loss from operations	(8,932)	(7,550)	(26,610)	(23,205)
Other income and expense:				
Other income, net	186	7	429	19
Interest income	446	292	1,575	371
Other income, net	632	299	2,004	390
Net loss before taxes	(8,300)	(7,251)	(24,606)	(22,815)
Income tax benefit	—	—	29	—
Net loss	$ (8,300)	$ (7,844)	$ (24,577)	$ (15,564)
Net loss per share:				
Basic and diluted	$ (1.04)	$ (0.86)	$ (3.01)	$ (2.73)
Weighted average number of common shares outstanding:				
Basic and diluted	7,978,457	8,388,029	8,161,904	8,371,449
Other comprehensive loss:				
Unrealized gain on short-term investments	7	—	5	—
Total comprehensive loss	$ (8,293)	$ (7,251)	$ (24,572)	$ (22,815)

Exhibit 99.1

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

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 35,557	$ 56,007
Short-term investments	7,137	11,352
Prepaid expenses and other current assets	4,581	4,427
Other receivables	172	223
Total current assets	47,447	72,009
Non-current assets:		
Property and equipment, net	36	53
Right-of-use asset	268	230
Total assets	$ 47,751	$ 72,292
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 488	$ 275
Accrued expenses	5,502	6,200
Current portion of lease liability	126	233
Total current liabilities	6,116	6,708
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	143	—
Total liabilities	12,259	12,708
Commitments and contingencies:		
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at September 30, 2023 and December 31, 2022; issued and outstanding shares - 0 at September 30, 2023 and December 31, 2022	—	—
Common stock, $0.01 par value: Authorized shares - 75,000,000 at September 30, 2023 and December 31, 2022; issued 7,937,755 and 8,283,708 at September 30, 2023 and December 31, 2022, respectively and outstanding shares - 7,914,582 and 8,267,968 at September 30, 2023 and December 31, 2022, respectively	79	82
Treasury stock, at cost, 23,173 and 15,740 shares at September 30, 2023 and December 31, 2022, respectively	(196)	(170)
Additional paid-in capital	187,673	187,164
Accumulated deficit	(152,060)	(127,483)
Accumulated other comprehensive loss	(4)	(9)
Total stockholders' equity	35,492	59,584
Total liabilities and stockholders' equity	$ 47,751	$ 72,292