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

February 28, 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.

Item 8.01 Other Events.

On February 28, 2023, Lumos Pharma, Inc. issued a press release titled "Lumos Pharma Completes Patient Enrollment in Two Phase 2 OraGrowtH Trials Evaluating Oral LUM-201 in Moderate Idiopathic PGHD."

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated February 28, 2023, entitled "Lumos Pharma Completes Patient Enrollment in Two Phase 2 OraGrowtH Trials Evaluating Oral LUM-201 in Moderate Idiopathic PGHD"

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: February 28, 2023

LUMOS PHARMA, INC.,
a Delaware corporation

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

Lumos Pharma Completes Patient Enrollment in Two Phase 2 OraGrowtH Trials Evaluating Oral LUM-201 in Moderate Idiopathic PGHD

Phase 2 OraGrowtH210 and Phase 2 PK/PD OraGrowtH212 Trials Are Fully Enrolled

Primary Outcome Data for Both OraGrowtH Trials Expected 4Q 2023

AUSTIN, TX, February 28, 2023 – Lumos Pharma, Inc. (NASDAQ:LUMO), a biopharmaceutical company advancing an oral therapeutic candidate for Pediatric Growth Hormone Deficiency (PGHD) through Phase 2 clinical trials, announced today that the last subjects have been enrolled and randomized in the Company's OraGrowtH210 and OraGrowtH212 trials evaluating LUM-201 for the treatment of moderate idiopathic PGHD. The Company now expects data on 82 subjects in the OraGrowtH210 Trial and 22 subjects in the PK/PD OraGrowtH212 Trial.

"We are very pleased to have reached these important milestones, which will allow us to complete our OraGrowtH trials and announce top line results in the fourth quarter of 2023," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "The interim data we announced in November showed that in the 1.6 mg/kg/day LUM-201 arm in the OraGrowtH210 study, mean annualized height velocity of 8.6 cm/yr was observed, in line with 8.3 – 8.6 cm/yr expected based on growth on rhGH for moderate PGHD subjects consistently observed in multiple large datasets. We look forward to building on these initial data, reporting primary outcome results, and continuing to advance our clinical program and planning for our pivotal Phase 3 trial for potentially the first oral therapeutic for PGHD."

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. 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 utility 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 82 subjects is anticipated in the fourth quarter of 2023. Subjects will be treated for up to 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 primary objective of the OraGrowthH212 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 22 subjects. Subjects will be allowed to remain on treatment until they reach their near-adult height. Primary data readout in 22 subjects is anticipated in the fourth quarter of 2023.

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 subjects who have completed the OraGrowthH210 Trial. Subjects are administered LUM-201 at a dose level of 3.2 mg/kg/day for up to 12 months. This trial is currently enrolling subjects.

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. 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 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 OraGrowthH210 and OraGrowthH212 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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