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

Date of Report (Date of earliest event reported): July 21, 2021 (July 20, 2021)

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

Delaware	**001-35342**	**42-1491350**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4200 Marathon Blvd., Suite 200 **Austin, TX**	**78756**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(512) 215-2630**

(Former name or former address, if changed since last report.)

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). ☐

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 8 - Other Events

Item 8.01. Other Events.

On July 20, 2021, Lumos Pharma, Inc. issued a press release titled “Lumos Pharma Announces Clinical Updates.”

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

Section 9 - Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated July 20, 2021, entitled "Lumos Pharma Announces Clinical 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: July 21, 2021

LUMOS PHARMA, INC.,
a Delaware corporation

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

Lumos Pharma Announces Clinical Updates

- *OraGrowthH210 Trial in PGHD primary outcome 6-month data now anticipated in 2H2023; treatment period to be extended to 12 months*
- *OraGrowthH212 PK/PD Trial initiated in Q2 2021; treatment period to be extended to 12 months with primary data at 6-months*
- *Cash balance as of June 30, 2021 of $107.7 million (unaudited) expected to be sufficient to support operations through primary data readouts for OraGrowthH210 and OraGrowthH212 Trials*
- *Conference Call to be held Wednesday, July 21, 2021 at 8:30 AM ET*

AUSTIN, TX, July 20, 2021 - Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, announces an update on clinical activities.

Phase 2 OraGrowthH210 Trial Primary 6-Month Data Expected 2H2023; Treatment period to be Extended to 12 Months

The Company is issuing new guidance concerning the Phase 2 OraGrowthH210 Trial of LUM-201 in PGHD. The pace of site initiation and enrollment of the trial has been slower than anticipated primarily due to COVID-19 restrictions. This impact has been particularly pronounced at international sites where faster patient enrollment was anticipated. Given slower enrollment, the 6-month primary outcome data for OraGrowthH210 are now anticipated in the second half of 2023. The trial's primary outcome continues to be the preliminary validation of our Predictive Enrichment Markers (PEM) strategy. From the trial, we will also select the optimal dose for a pivotal Phase 3 study in PGHD.

Given the novel mechanism of action of LUM-201 compared to other growth hormone therapies, the FDA has now requested an extension of the OraGrowthH210 Trial to 12 months. The planned protocol extension mirrors the first six months of the OraGrowthH211 long-term extension study. The FDA has placed our planned long-term extension study on partial clinical hold until additional efficacy data from the OraGrowthH210 Trial are available to be reviewed. We are currently reviewing the timing of the start of the long-term extension study in context of the OraGrowthH210 Trial extension. We do not anticipate these protocol changes, on a stand-alone basis, to extend the time to the initiation of our Phase 3 clinical trial.

PK/PD OraGrowtH212 Trial of LUM-201 in PGHD Initiated Q2 2021; Treatment Period to be Extended to 12 Months

The OraGrowtH212 Trial was initiated in June and is currently enrolling patients. This study will evaluate the pharmacokinetic and pharmacodynamic (PK/PD) effects of LUM-201 in PGHD patients at two dose levels to confirm prior clinical data illustrating the increased pulsatile release of endogenous growth hormone unique to LUM-201 and its potential for this mechanism of action to contribute to efficacy in PGHD. This open-label trial will be extended from six months to twelve months to capture additional PK/PD and height velocity data. The PD pulsatility assessment will continue to be at six months on therapy as planned.

“While Covid-19 has had an impact on enrollment, as we continue to open international sites for our Phase 2 OraGrowtH210 Trial, we expect the pace of patient screenings to accelerate,” commented Rick Hawkins, Chairman, CEO and President of Lumos Pharma. “We look forward to the primary outcome readout of this trial in the second half of 2023. Though the FDA’s request for a six-month extension to our OraGrowtH210 Trial was unexpected, we are confident that our trial protocol changes will both add impactful data and meet the FDA’s request. We also remain confident in our Predictive Enrichment Markers strategy with respect to our OraGrowtH210 and OraGrowtH212 Trials. Our OraGrowtH212 Trial is up and running and patient enrollment has begun for that trial as well. With a solid financial foundation in place, we believe we have sufficient cash to support operations through the primary outcome readouts for both OraGrowtH210 and OraGrowtH212 Trials.”

Conference Call and Webcast Details

The Company has scheduled a conference call and webcast for Wednesday, July 21 at 8:30 a.m. ET today to discuss clinical activities. 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/exvigvh6. 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 3198435. 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 daily injections that current PGHD patients 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. (the "Company") 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. The words "forecast," "projected," "guidance," "upcoming," "will," "would," "plan," "intend," "anticipate," "approximate," "expect," "potential," "imminent," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, the ability of prior research results to forecast the performance of therapeutic agents in the clinic, anticipated business development activities, anticipated market reception to our treatment regimen for PGHD and other indications, plans related to initiation, enrollment, and execution of clinical trials, anticipated results and timing of results from our 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 its operating requirements; and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that the Company makes due to a number of important factors, including the effects of pandemics or other widespread health problems, 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 as discussed in "Risk Factors" and elsewhere in Lumos Pharma's Annual Report on Form 10-K for the year ended December 31, 2020 and other reports filed with the SEC. The forward-looking statements in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause their views to change. However, while it may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing the Company's views as of any date subsequent to the date of this press release.

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