

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): June 28, 2021

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

Delaware
(State or other jurisdiction
of incorporation)

001-35342
(Commission
File Number)

42-1491350
(IRS Employer
Identification No.)

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

78756
(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 June 28, 2021, Lumos Pharma, Inc. issued a press release titled “Lumos Pharma Announces OraGrowthH212 Trial of LUM-201 in PGHD is Open for Enrollment.”

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 June 28, 2021, entitled " Lumos Pharma Announces OraGrowth212 Trial of LUM-201 in PGHD is Open for Enrollment "

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: June 28, 2021

LUMOS PHARMA, INC.,
a Delaware corporation

By: /s/ Richard J. Hawkins

Richard J. Hawkins

Its: Chief Executive Officer



For Immediate Release

Lumos Pharma Announces OraGrowthH212 Trial of LUM-201 in PGHD Is Open for Enrollment

Single-Center Phase 2 Trial to Study the Pharmacokinetics/Pharmacodynamics (PK/PD) and Unique Pulsatile Mechanism of Action of LUM-201 at Two Dose Levels

AUSTIN, TX, June 28, 2021 - [Lumos Pharma, Inc.](#) (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, announced today that the OraGrowthH212 Trial, a Phase 2 PK/PD study of the company's lead asset LUM-201 for the treatment of patients with pediatric growth hormone deficiency (PGHD), is open for enrollment.

Lumos Pharma believes an increase in the pulsatile release of endogenous growth hormone (GH) has the potential to produce a substantial improvement in height velocity in PGHD patients. The primary goal of our OraGrowthH212 Trial will be to document PK/PD data showing both a dose-related response and increased pulsatile release of GH in response to LUM-201 in a moderately growth hormone deficient subset of pediatric patients with PGHD. Similar PK/PD data showing a dose-related response and increased pulsatile release of GH was previously documented in Phase 2 studies conducted by Merck in adults and in a small subset of PGHD patients. The OraGrowthH212 Trial is being conducted at the Research Institute of Mother and Child Care, an institute of the University of Chile, at the San Borja Arriaran Clinical Hospital, a specialized pediatric center with the ability to perform the more frequent sample collection and monitoring required for this type of clinical trial.

"We are excited to announce the opening of the OraGrowthH212 Trial" said Rick Hawkins, CEO, President and Chairman of Lumos Pharma. "This study, run in parallel with our Phase 2b OraGrowthH210 Trial, should confirm the unique pulsatile mechanism of action of LUM-201 and its potential for efficacy in moderate PGHD patients. While this trial is not required as part of the regulatory process, we hope that it will provide supportive data for future regulatory filings and commercial marketing efforts."

The study, [*A Single-Center, 6-Month, Randomized, Open-Label, Parallel Arm Study of Daily Oral LUM-201 in Naïve-to-Treatment, Prepubertal Children with Pediatric Growth Hormone Deficiency*](#), will evaluate the pharmacokinetic (PK) and pharmacodynamic (PD) effects of LUM-201 in 24 PGHD patients randomized to two separate dose cohorts: 1.6 mg/kg/day and 3.2 mg/kg/day. Patients will have their baseline levels of growth hormone secretion measured every ten minutes over a 12-hour period prior to starting their randomized LUM-201 treatment for 6 months. Following 6 months of treatment, patients will again have a 12-hour assessment of growth hormone levels to measure LUM-201's amplification of pulsatile growth hormone secretion. Primary outcome measures are evaluation of augmented growth hormone pulsatility and pharmacokinetics of LUM-201. Safety data and height standard deviation score (SDS) will also be evaluated as secondary outcome measures.

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 2b clinical trial, the OraGrowtH210 Trial, and a PK/PD clinical trial, 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," "should," "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 market reception to our treatment regimen for PGHD and other indications, plans related to initiation and execution of clinical trials; results of operations 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, the ability to obtain the necessary patient enrollment for our product candidate in a timely manner, the ability to successfully develop our product candidate 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 and the Company'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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