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): March 4, 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). o

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 o

Section 8 - Other Events

Item 8.01. Other Events.

On March 4, 2021, Lumos Pharma, Inc. issued a press release titled "Data Supporting Use of Predictive Enrichment Markers for Lumos Pharma's LUM-201 Therapy in Clinical Trials for Moderate PGHD Published in Journal of the Endocrine Society"

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 March 4, 2021, entitled "Data Supporting Use of Predictive Enrichment Markers for Lumos Pharms's LUM-201 Therapy in Clinical Trials for Moderate PGHD Published in Journal of the Endocrine Society"

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: March 4, 2021

LUMOS PHARMA, INC.,
a Delaware corporation

By: /s/ Carl W. Langren
Carl W. Langren
Its: Chief Financial Officer

Data Supporting Use of Predictive Enrichment Markers for Lumos Pharma's LUM-201 Therapy in Clinical Trials for Moderate PGHD Published in Journal of the Endocrine Society

Data Analysis Supports Use of Predictive Enrichment Markers in Phase 2b OraGrowtH210 Trial

AUSTIN, TX, March 4, 2021 - Lumos Pharma, Inc. (NASDAQ: LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, announced that results of peer-reviewed analyses of data from two prior pediatric growth hormone deficiency (PGHD) studies have been published in the *Journal of the Endocrine Society* (JES). The retrospective studies provide support for the use of predictive enrichment markers (PEMs) in clinical trials to assess the patient population likely to benefit from treatment with LUM-201.

In a manuscript by George M. Bright, MD, *et al*, entitled, *Development of a Predictive Enrichment Marker for Oral GH Secretagogue LUM-201 in Children with Growth Hormone Deficiency*, a peer-reviewed analysis of the data from a clinical trial previously conducted by Merck (the Merck 020 study) was performed. The Merck 020 study was a placebo-controlled trial of LUM-201 and recombinant human growth hormone (rhGH) in which all randomized subjects had pretreatment testing, including IGF-1 and peak GH levels determined after a single dose of LUM-201. In subsequent analysis of this data set, two markers suitable for enriching in LUM-201 responsive patients (termed Predictive Enrichment Markers or PEMs) were identified, baseline IGF-1 cut-off level > 30 ng/ml and peak GH level ≥ 5 ng/mL after a single oral dose of LUM-201. The cut-off values for GH were arrived at using a receiver operator characteristic curve or ROC analysis and the IGF-1 cut-offs were determined using an iterative filtering approach. Additionally, those who did not meet our criteria and did not respond well to LUM-201 treatment grew very well on the standard of care, rhGH. The PEMs identified from the analysis of the Merck 020 study data are being used prospectively to select PGHD patients for enrollment in our ongoing OraGrowtH210 Trial.

In a manuscript by Werner F. Blum, PhD, *et al*, entitled, *Corroboration Between Prediction Enrichment Markers for Height Velocity to rhGH and an Oral GH Secretagogue Treatment in Children with Moderate GHD*, researchers conducted a data-mining analysis of children with growth hormone deficiency (GHD) in the GeNeSIS legacy database – a prospective, open-label, observational research program conducted by Eli Lilly between 1999 and 2015. The purpose of the data mining analysis was to evaluate if baseline IGF-1 and stimulated peak growth hormone were independent predictors of 12-month height velocity in children with idiopathic growth hormone deficiency. The analysis corroborated the use of these PEMs as meaningful indicators of the severity of GHD and the response to treatment with rhGH, with researchers concluding that "IGF-1 and stimulated GH alone or together are significant indicators of the degree of pediatric GHD, independent of other markers." This manuscript's definition of patients with moderate GHD is aligned with the baseline IGF-1 and peak GH levels noted above. This analysis also illustrated that approximately 60% of the total diagnosed pediatric GHD patient population meet our definition of PEM-positive, i.e. they are moderately GHD deficient and are believed likely to respond to LUM-201.

Additionally, these data illustrate the differential first-year response to rhGH between the more severely deficient (PEM-negative) patients with a mean height velocity (HV) of 9.6 cm/yr compared to 8.3 cm/yr in the moderately GH deficient patients (PEM-positive). The distinct response the moderate and more severe patient subsets have to rhGH treatment highlights their differing physiologies and alludes to why the moderate group may be more responsive to LUM-201.

“We believe these data support our ongoing Phase 2b OraGrowtH210 Trial design, where we will use these PEMs to select patients and 0.8, 1.6, and 3.2mg/kg LUM-201 doses to confirm our PEM strategy and determine the optimal dose for a Phase 3 registration trial,” said Rick Hawkins, Chairman, CEO and President of Lumos Pharma. “We are confident that the OraGrowtH210 Trial will provide further evidence that oral LUM-201 can provide results for appropriately selected patients without the daily or weekly injections involved with current therapy.”

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, 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, our intent to initiate a Pharmacokinetic/Pharmacodynamic OraGrowtH212 study of LUM-201 in PGHD in 2021, that cash on hand is expected to fund current operations through the read-out of our Phase 2b OraGrowtH210 Trial and completion of the OraGrowtH212 Trial, that we are engaging in activities that we hope will lead to the expansion of our pipeline through the licensure of other rare disease assets, that we believe Lumos Pharma is well positioned to execute on our clinical and business development plans, the potential of an orally administered treatment regimen for PGHD and other indications, plans related to 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 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 such as the ongoing COVID-19 pandemic, the outcome of our future interactions with regulatory authorities, the outcome of our Phase 2b OraGrowtH210 Trial for LUM-201, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the availability

of sufficient resources for our operations and to conduct or continue planned clinical development programs, 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 risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as LUM-201 that are safe and effective for use as human therapeutics, the timing and ability of Lumos to monetize its priority review voucher and 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, the Company's Annual Report on Form 10-K for the year ended December 31, 2019 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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