

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

May 8, 2023
Date of Report (date of earliest event reported)

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

Delaware
(State or other jurisdiction of incorporation or organization)

001-35342
(Commission File Number)

42-1491350
(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 May 8, 2023, Lumos Pharma, Inc. issued a press release titled "Encouraging Data from Lumos Pharma OraGrowth Trials Presented at Annual Pediatric Endocrine Society Meeting (PES)."

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 May 8, 2023, entitled " Encouraging Data from Lumos Pharma OraGrowtH Trials Presented at Annual Pediatric Endocrine Society Meeting (PES). "

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: May 8, 2023

LUMOS PHARMA, INC.,
a Delaware corporation

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



Encouraging Data from Lumos Pharma OraGrowth Trials Presented at Annual Pediatric Endocrine Society Meeting (PES)

Oral and Poster Presentations on OraGrowth Trials at PES 2023 Further Support Potential for LUM-201 as First Oral Treatment for Moderate Idiopathic PGHD

OraGrowth212 Interim Data Demonstrate LUM-201 Amplifies Natural Pulsatile GH-Secretion and that IGF-1 SDS and Serum Concentrations Remain within Normal Range

AUSTIN, TX, May 8, 2023 – [Lumos Pharma, Inc.](#) (NASDAQ:LUMO), a biopharmaceutical company advancing an oral therapeutic candidate for idiopathic Pediatric Growth Hormone Deficiency (iPGHD) through Phase 2 clinical trials, announced today that interim data from its OraGrowth210 Trial were reviewed in an oral presentation at the 2023 Annual Meeting of the [Pediatric Endocrine Society \(PES\)](#), held in San Diego, California, May 5-8, 2023. Data from the interim analysis of its OraGrowth212 Trial were also presented in a poster session during the conference.

Oral Presentation on Phase 2 Dose-finding OraGrowth210 Trial ([link](#))

- Title (Abstract 6178) – *Growth Response to LUM-201 in the OraGrowth210 Trial in Idiopathic Pediatric Growth Hormone Deficiency (iPGHD): Interim Analysis Data (41 Subjects)*
- Lead Author – Andrew Dauber, MD, Chief of Endocrinology, Children’s National Medical Center, Washington, D.C.
- Conclusions:
 - In a selected patient population (idiopathic PGHD) using the LUM-201 PEM (Prediction Enrichment Marker), LUM-201 demonstrates an increase in height velocity with three doses of this oral growth hormone secretagogue.
 - Oral LUM-201 1.6 mg/kg/day cohort grew 8.6 cm/year, in line with the expected historical rate of ~ 8.3 - 8.6 cm/year from prior data of moderate iPGHD rhGH treated patients.
 - No treatment-related Serious Adverse Events (SAEs) and no meaningful safety signals observed in either laboratory values, adverse event data, or in electrocardiogram values.

Poster Presentation on Phase 2 PK/PD Mechanistic OraGrowth212 Trial ([link](#))

- Title (Abstract 6197) – *Observed Serum IGF-1 Concentration Increase Within Normal Range After Prolonged Daily Oral LUM-201 Administration in Idiopathic Pediatric Growth Hormone Deficiency from the OraGrowth212 Trial: Interim Analysis Data*
- Lead Author – Fernando Cassorla, MD, Chief of Pediatric Endocrinology, University of Chile
- Conclusions:

- o LUM-201, at doses of 1.6 mg/kg/day and 3.2 mg/kg/day, increases the natural pulsatile release of GH in children with iPGHD.
- o These increases in GH AUC in turn stimulate an increase in IGF-1 and IGF-1 SDS, which increases growth in children with iPGHD; all subjects demonstrated an increase in AHV.
- o Both of the doses of LUM-201 showed acceptable safety and tolerability.
- o The preliminary optimal dose, based on the controlled dose range finding study, OraGrowthH210 Trial, is 1.6 mg/kg/day, as it produced increases in AHV that were comparable to the higher dose of 3.2 mg/kg/day.
- o Given the modest imbalance in baseline demographics, including baseline AHV, between the two dose groups in the OraGrowthH212 interim analysis, the 6, 9, and 12-month AHV values appear to be comparable in the trial.
- o Due to the natural negative feedback mechanisms, even doubling the optimal dose from 1.6 to 3.2 mg/kg/day did not result in IGF-1 SDS values outside of the normal range.
- o The increase in AHV over 6 months in the OraGrowthH212 Trial appears to be primarily related to lower baseline AHV than dose.
- o Pending the final analysis in 4Qtr 2023, the optimal dose currently appears to be 1.6 mg/kg/day.

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 several Phase 2 clinical trials for the treatment of idiopathic Pediatric Growth Hormone Deficiency (iPGHD): the dose-finding OraGrowthH210 Trial; the PK/PD mechanistic OraGrowthH212 Trial; and a switch trial, the OraGrowthH213 Trial. 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 progress in our clinical efforts including comments concerning screening and enrollment for our trials, expecting the primary outcome data readout for our trials, anticipated market reception to our treatment regimen for PGHD and other indications, plans related to initiation and execution of 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. Forward-looking statements contained in this announcement are made as of this date and Lumos undertakes no duty to update such information except as required under applicable law. 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 in the "Risk Factors" section and elsewhere in Lumos Pharma's Annual Report on Form 10-K for the year ended December 31, 2022, as well as other reports filed with the SEC including our Quarterly Reports on Form 10-Q. 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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