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

September 26, 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 September 26, 2023, Lumos Pharma, Inc. issued a press release titled "Lumos Pharma Announces New Data and Analysis of 15 Subjects from OraGrowtH212 Trial Presented at the 2023 ESPE Annual Meeting."

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 September 26, 2023, entitled "Lumos Pharma Announces New Data and Analysis of 15 Subjects from OraGrowtH212 Trial Presented at the 2023 ESPE Annual Meeting."

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: September 26, 2023

LUMOS PHARMA, INC.,
a Delaware corporation

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

Exhibit 99.1

Lumos Pharma Announces New Data and Analysis of 15 Subjects from OraGrowtH212 Trial Presented at the 2023 ESPE Annual Meeting

- *Deconvolution Analysis Shows 60% Increase in GH Secretion, Comparable to Established Values in Normal Children*
- *Analysis Shows Annualized Height Velocity Increased ~62% Compared to Baseline*
- *Data Support LUM-201 Mechanism of Action in Moderate PGHD Patient Population*

AUSTIN, TX, September 26, 2023 – Lumos Pharma, Inc. (NASDAQ:LUMO), a biopharmaceutical company advancing an oral therapeutic candidate for moderate Pediatric Growth Hormone Deficiency (PGHD) through Phase 2 clinical trials, announced today that an analysis of interim data from its OraGrowtH212 Trial was given as an oral presentation at the 2023 annual meeting of the European Society for Paediatric Endocrinology (ESPE), held in The Hague, Netherlands, September 21-23, 2023.

"These new data and analysis of interim data from our OraGrowtH212 trial show that oral LUM-201 restored GH secretion to similar levels seen in normally growing children by enhancing endogenous pulsatile GH secretion while maintaining normal feedback control of IGF-1," said John C. McKew, PhD, President and Chief Scientific Officer of Lumos. "The presented results add to the growing body of evidence supporting the physiologic mechanism of action for LUM-201, as well as its potential as a treatment for moderate PGHD. As we look ahead to our topline data readout from these trials in the fourth quarter, these results and the others we have released recently add to our confidence that at least one of the LUM-201 dose cohorts will meet growth expectations based on historical averages, and that the LUM-201 mechanism of action and potency can elicit sustained improvements in growth in the moderate PGHD patient population. We look forward to our topline data announcement and to continuing to advance our LUM-201 clinical program as potentially the first oral therapeutic for PGHD."

The oral presentation, *Deconvolution Analysis: Oral GH secretagogue (LUM-201) enhances growth in individuals with moderate Pediatric Growth Hormone Deficiency (PGHD) by enhancing endogenous GH secretion and increasing IGF-1* (Fernando Cassorla, MD, et al), was given in a late breaking session, Saturday, September 23, 9:30-10:30 AM CET (Local Time). The slides presented at ESPE are available on the Posters & Publications page under the Investors & Media section of Lumos Pharma's website.

The objective of the analysis was to characterize growth hormone (GH) profiles, defined by deconvolution analysis, based on the GH concentration sampled over 12 hours at baseline and after 6 months of therapy with daily oral LUM-201 to illustrate how LUM-201 increases annualized height velocity (AHV), total GH secretion, and serum IGF-1 and IGFBP3 in individuals with moderate PGHD. Fifteen prepubertal, naive moderate PGHD subjects were screened with a predictive enrichment marker (PEM) test to assess their acute response to oral LUM-201 (0.8mg/kg), with a positive test having a peak GH ≥5 ng/ml with a basal IGF-1 >30 ng/ml. At baseline, subjects (10M:5F)

were (mean ± SD) aged 7.9±1.4 years, with IGF-1 SDS -0.82±0.9, and peak GH 7.2±2.2 ng/mL (clonidine stimulation), consistent with moderate PGHD.

Deconvolution analysis was performed on serum GH measured every 10 minutes (0800 h to 2000 h). Patients were randomized to receive 1.6 mg/kg/day or 3.2 mg/kg/day of oral LUM-201. Both baseline characteristics and acute GH responses to the PEM test (p=0.9) and the day 1 PEM test doses were not different between the groups (34.8±6.6 ng/ml for 1.6mg/kg and 38.2±11.2 ng/ml for 3.2mg/kg, p=0.7). The groups were therefore combined in this analysis.

Results showed that after 6 months of treatment with LUM-201, GH, IGF parameters, and AHV increased 60-80% (see Table 1 for means (SD)) from baseline. The study author concluded that LUM-201 enhanced pulsatile GH secretion to similar levels observed in normal growing children (estimated at ~3.5 µg/kg/12h; Albertsson-Wikland et al JCEM 1994), and that restoration of physiological pulsatile GH secretion and IGF-1 were sufficient to support normal growth. The study's author further noted that LUM-201 in the potential treatment of moderate PGHD has the advantages of being taken orally, enhancing endogenous pulsatile GH secretion, and therefore maintaining normal feedback mechanisms to restore more physiological growth.

Table 1	Baseline	6 Month	t test, p value
GH total*	1.45 (0.89)	2.32 (1.25)	0.013
GH pulsatile*	1.28 (0.83)	1.93 (1.17)	0.035
GH basal *	0.17 (0.11)	0.40 (0.28)	0.008
AHV (cm/year)	4.7 (1.3)	7.6 (1.1)	< 0.00001
IGF-1 (ng/mL)	115.5 (46.6)	205.4 (63.9)	0.0004
IGFBP3 (nmol/L)	139.3 (32.6)	169.0 (30.1)	0.0004
IGF-1:IGFBP3	0.108 (0.031)	0.157 (0.050)	0.0044
**daytime secretion µg/kg body weight per 12hr*			

About PGHD and the Therapeutic Landscape

PGHD is the consequence of inadequate secretion of growth hormone from the pituitary gland in children resulting in low growth hormone (GH) in the body, insufficient production of downstream signaling molecules required for growth, and the subsequent lack of growth. The prevailing standard of care for PGHD consists of a daily injection of exogenous GH administered for approximately 7 years on average. Several once-weekly injectable GH therapies have recently been approved in the US and internationally to treat PGHD. LUM-201, also known as ibutamoren, is an orally administered investigational small molecule that promotes the secretion of GH from the pituitary gland and represents an opportunity for appropriately selected patients to avoid the daily or weekly injections involved with current or forthcoming therapies. LUM-201 has been observed to increase the amplitude of endogenous pulsatile GH secretion, which mimics the natural pattern of GH secretion.

About Lumos Pharma

Lumos Pharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of therapeutics for rare diseases. The Company was founded and is led by a management team with longstanding experience in rare disease drug development. Lumos Pharma's lead therapeutic candidate, LUM-201, is a novel, oral growth hormone (GH) secretagogue, seeking to transform the ~$3.4B global GH market from injectable to oral therapy. LUM-201 is currently being evaluated in multiple Phase 2 clinical studies in Pediatric Growth Hormone Deficiency (PGHD) and 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 therapeutics that are safe, efficacious, and offer a 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, progress in our clinical efforts including the timing of expected results on our LUM-201 trials and our ability to continue advancing our trials, encouraging interim data and new analysis presented, that our convictions are further reinforced that at least one of the LUM-201 dose cohorts will meet growth expectations based on historical averages, that the LUM-201 mechanism of action and potency can elicit sustained improvements in growth in the moderate PGHD patient population, continuing to advance our LUM-201 clinical program for potentially the first oral therapeutic for PGHD, 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 outcome of our future interactions with regulatory authorities, the timing and ability of Lumos to raise additional equity capital as needed to fund our Phase 3 Trial or for other purposes, 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 effects of pandemics, other widespread health problems or military conflicts including the Ukraine-Russia conflict 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, 2022, as well as other reports filed with the SEC. 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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Investor & Media Contact:

Lisa Miller
Lumos Pharma Investor Relations
512-792-5454
ir@lumos-pharma.com