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 6, 2022 (May 5, 2022)
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.

Section 8 - Other Events

Item 8.01 Other Events.

On May 5, 2022, Lumos Pharma, Inc. issued a press release titled "Lumos Pharma Announces a Clinical Collaboration with Massachusetts General Hospital (MGH) to Evaluate Oral LUM-201 in Nonalcoholic Fatty Liver Disease (NAFLD) in a Phase 2 Investigator-Initiated Trial."

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 May 5, 2022, entitled "Lumos Pharma Announces a Clinical Collaboration with Massachusetts General Hospital (MGH) to Evaluate Oral LUM-201 in Nonalcoholic Fatty Liver Disease (NAFLD) in a Phase 2 Investigator-Initiated Trial"

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 6, 2022

LUMOS PHARMA, INC.,
a Delaware corporation

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

FOR IMMEDIATE RELEASE

Lumos Pharma Announces a Clinical Collaboration with Massachusetts General Hospital (MGH) to Evaluate Oral LUM-201 in Nonalcoholic Fatty Liver Disease (NAFLD) in a Phase 2 Investigator-Initiated Trial

– The IND application for this pilot trial to evaluate oral growth hormone secretagogue, LUM-201, in NAFLD has been approved by the FDA -

AUSTIN, TX, May 5, 2022 (GLOBE NEWSWIRE) – Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, initially targeting pediatric growth hormone deficiency, today announced a collaboration with Laura Dichtel, MD of Massachusetts General Hospital to evaluate the orally administered growth hormone (GH) secretagogue, LUM-201, in Nonalcoholic Fatty Liver Disease (NAFLD). The investigational new drug (IND) application for this pilot trial has received a study may proceed letter by the FDA.

“I look forward evaluating the use of LUM-201 for patients with NAFLD," said Laura Dichtel, MD, Assistant Professor, Harvard Medical School, Department of Endocrinology, Neuroendocrine Unit. "Prior studies have demonstrated growth hormone’s potential to treat NAFLD, given the hormone’s lipolytic actions in addition to its role as an anti-inflammatory cytokine. Based on these findings, LUM-201, an oral growth hormone secretagogue, could prove to be an efficacious therapeutic for those suffering from this chronic liver disease.”

“Lumos Pharma is honored to partner with Dr. Dichtel and Massachusetts General Hospital to evaluate LUM-201 in NAFLD,” commented Rick Hawkins, CEO and Chairman of Lumos Pharma. “Nonalcoholic fatty liver disease is estimated to be prevalent in approximately 25% of adults worldwide. Hepatic steatosis can progress to nonalcoholic steatohepatitis (NASH) with fibrosis, and NASH-associated liver failure is one of the leading causes of liver transplant in the United States. While we remain focused on our core LUM-201 program in PGHD and identifying the next therapeutic area for LUM-201, we are pleased to support Mass General’s exploration of additional indications for LUM-201.”

This investigator-initiated Phase 2 trial is a single-site, 6-month, open-label pilot study of daily oral LUM-201 in adults with NAFLD. The trial will evaluate a dose of 25 mg/day of LUM-201 in 10 men and women with NAFLD. GH is a critical stimulator of lipolysis, and preclinical data suggest that amplifying GH secretion has the potential to reduce hepatic steatosis and prevent NAFLD progression. Interestingly, enhancing the natural pulsatile release of GH has been shown clinically in short-term studies to be more efficacious in inducing lipolysis than continuous infusions of GH. The primary endpoints will be to determine the changes in both intrahepatic lipid content and hepatic inflammation and fibrosis with growth hormone (GH) augmentation as measured by ^{1}H-MRS and Perspectum’s Liver*MultiScan*®. Perspectum’s LiverMultiScan® is the leading non-invasive digital tool for liver diagnostics, giving physicians key indications of liver tissue characteristics to empower their diagnostic and patient management decisions. Biopsies will be conducted on a subset of patients to obtain additional information at the genetic and cellular level in this indication.

Lumos Pharma approved an unsolicited grant application for this study and will supply LUM-201 for this pilot trial. Lumos Pharma has a pending application for a method-of-use patent for LUM-201 in NAFLD and retains all intellectual property rights for LUM-201 in this indication.

About LUM-201

LUM-201 (ibutamoren) is an orally administered small molecule that promotes the secretion (secretagogue) of Growth Hormone (GH) from the pituitary gland.[1] LUM-201 acts as an agonist of the GH Secretagogue Receptor to stimulate GH release and to suppress the release of somatostatin.[2] LUM-201 has been observed to increase the amplitude of endogenous

pulsatile GH secretion in humans, which mimics the natural pattern of GH secretion.[3,4] This therapeutic candidate has been studied in more than 1,200 patients, both adult and pediatric, and was generally well tolerated with the most commonly reported adverse events being digestive systems events, including appetite increase. Mild elevations in liver enzymes without accompanying changes in bilirubin were also reported. LUM-201 has received Orphan Drug Designation in both the US and EU.

About Nonalcoholic Fatty Liver Disease (NAFLD)

Nonalcoholic fatty liver disease (NAFLD) is a buildup of excess fat in the liver (hepatic steatosis) in the absence of significant alcohol consumption. Hepatic steatosis can progress to nonalcoholic steatohepatitis (NASH) with fibrosis, and NASH-associated liver failure is one of the leading causes of liver transplant in the United States. It is estimated that approximately 25% of the worldwide adult population have NAFLD and an estimated 1.5-6.4% of the worldwide adult population have NASH.[5]

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 recombinant growth hormone injections that PGHD patients 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/.

[1] Patchett A.A., et al. Design and Biological Activities of L-163,191 (MK-0677): A Potent, Orally Active Growth Hormone Secretagogue, Proc Natl Acad Sci, 1995, 92:7001-7005.

[2] Howard A.D., et al. A Receptor in Pituitary and Hypothalamus that Functions in Growth Hormone Release, Science, 1996, 273:974-977.

[3] Nass R., et al. Effects of an Oral Ghrelin Mimetic on Body Composition and Clinical Outcomes in Healthy Older Adults, Ann Intern Med, 2008, 149:601-611.

[4] Chapman I.M., et al. Oral Administration of Growth Hormone (GH) Releasing Peptide-Mimetic MK-677 Stimulates the GH/Insulin-Like Growth Factor-I Axis in Selected GH-Deficient Adults, J Clin Endocrinol Metab, 1997, 82(10):3455-3463.

[5] Younossi Z.M., et al. Global epidemiology of nonalcoholic fatty liver disease – Meta-analytic assessment of prevalence, incidence, and outcomes. *Hepatology*, 2016;64(1):73-84.

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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 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, anticipating interim analyses of trials, expecting the primary outcome data readout for our trials, the potential to expand our LUM-201 platform into other indications, future financial performance, results of operations, cash usage and cash position and sufficiency of our cash resources to fund our operating requirements through the primary outcome data readout from the OraGrowthH210 and OraGrowthH212 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. In addition to other considerations referenced in this paragraph, the recent conflict between Ukraine and Russia has increased the uncertainty in that region and may impact our business in the future. Our forward-looking statements are neither historical facts nor assurances of future performance. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make due to a number of important factors, including the effects of pandemics, other widespread health problems or the Ukraine-Russia conflict, 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.

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, 2021, 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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Source: Lumos Pharma, Inc.