SECURITIES & EXCHANGE COMMISSION EDGAR FILING

9 METERS BIOPHARMA, INC.

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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):April 12, 2021

9 Meters Biopharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37797**	**27-3948465**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

8480 Honeycutt Road, Suite 120, Raleigh, NC 27615
(Address of principal executive offices) (Zip Code)

(919) 275-1933
(Registrant's telephone number, include area code)

N/A
(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:

☐ 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 $0.0001 Par Value	NMTR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 April 12, 2021, 9 Meters Biopharma, Inc. announced it will collaborate with the Celiac Disease Foundation to support clinical trial enrollment in its Phase 3 trial of larazotide in celiac disease. A copy of such release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
Exhibit 99.1	Press Release dated April 12, 2021.

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.

9 Meters Biopharma, Inc.

Date: April 12, 2021

By: /s/ Edward J. Sitar
Edward J. Sitar
Chief Financial Officer

PRESS RELEASE

9 Meters Biopharma, Inc. and Celiac Disease Foundation Announce Collaboration to Support Clinical Trial Enrollment in 9 Meters' Phase 3 CeDLara Study

RALEIGH, NC / ACCESSWIRE / April 12, 2021 / 9 Meters Biopharma, Inc. (NASDAQ:NMTR), a clinical-stage company focused on rare and unmet needs in gastroenterology, announced today that the Company will collaborate with the Celiac Disease Foundation (CDF) to support clinical trial enrollment in 9 Meters' Phase 3 study, CeDLara, for their drug candidate larazotide in celiac disease.

9 Meters' CeDLara study is a Phase 3 randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of 9 Meters' investigational drug, larazotide, for adult patients with at least a six-month history of celiac disease who continue to experience gastrointestinal symptoms despite maintaining a gluten-free diet for at least six months. Interim results and topline data readouts are anticipated in 2022.

"We look forward to working with the Celiac Disease Foundation to bring larazotide to more celiac disease patients through our CeDLara study. With no current treatments available for patients other than following a gluten-free diet (GFD), which is sometimes ineffective, larazotide has the potential to reduce painful symptoms in patients as an adjunctive therapy along with a GFD," said Patrick H. Griffin, M.D., Chief Medical Officer of 9 Meters. "With data showing larazotide as effective, safe and well tolerated in clinical studies to date, we're excited to continue advancing through our Phase 3 trial with the help of CDF."

Marilyn G. Geller, Chief Executive Officer of the Celiac Disease Foundation added, "There is abundant research proving that strict lifetime adherence to a gluten-free diet is an inadequate treatment for a vast number of celiac disease patients. On behalf of the patient community we represent, the Celiac Disease Foundation is gratified that a necessary alternative therapy to treat celiac disease is in Phase 3 clinical trials. We are pleased to partner with 9 Meters and deploy our unique assets to help enroll patients into this important clinical trial."

Celiac disease, an autoimmune functional GI disease characterized by an inflammatory response to dietary gluten, can cause severe and life-altering diarrhea, abdominal pain and gas. The only current treatment for the disease is following a GFD, which is insufficient for many patients due to the unintentional consumption of trace amounts of gluten found in many foods and cosmetic products. Larazotide, 9 Meters' oral, gut-restricted drug in development, works to prevent gluten breakdown from leaving the intestine and causing an inflammatory response when small amounts of gluten are consumed.

About 9 Meters Biopharma
9 Meters Biopharma, Inc. ("the Company") is a rare and unmet needs-focused gastroenterology company. The Company is advancing NM-002, a proprietary long-acting GLP-1 agonist into a Phase 2 trial for short bowel syndrome (SBS), a rare, orphan disease, as well as larazotide, a Phase 3 tight junction regulator being evaluated for patient-reported symptom improvement in non-responsive celiac disease.

For more information, please visit www.9meters.com or follow 9 Meters on Twitter and LinkedIn.

Forward-looking Statements
This press release includes forward-looking statements based upon the Company's current expectations. Forward-looking

statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future

events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: (i) uncertainties associated with the clinical development and regulatory approval of product candidates; (ii) risks related to the inability of the Company to obtain sufficient additional capital to continue to advance these product candidates and its preclinical programs; (iii) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (iv) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; (v) the impact of COVID-19 on our operations, clinical trials or future financings and (vi) risks associated with the possible failure to realize certain anticipated benefits of the Company's 2020 merger and its acquisition of Naia Rare Diseases, Inc. in 2020, including with respect to future financial and operating results. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements because of these risks and uncertainties. These and other risks and uncertainties are more fully described in periodic filings with the SEC, including the factors described in the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2020 and in other filings that the Company has made and future filings the Company will make with the SEC. You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof or as of the dates indicated in the forward-looking statements. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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