

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

9 METERS BIOPHARMA, INC.

Form: 8-K

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Corporate Issuer CIK: 1551986

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): August 12, 2020

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

Delaware
(State or other jurisdiction of
incorporation or organization)

001-37797
(Commission
File Number)

27-3948465
(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 2.02. Results of Operations and Financial Condition.

On August 12, 2020, 9 Meters Biopharma, Inc. issued a press release providing a business update and announcing second quarter 2020 results. 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.

Pursuant to General Instruction B.2 of Current Report on Form 8-K, the information contained in, or incorporated into, Item 2.02, including the press release attached as Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
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Exhibit 99.1	Press Release dated August 12, 2020.
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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: August 12, 2020

By: /s/ Edward J. Sitar

Edward J. Sitar

Chief Financial Officer

9 Meters Biopharma, Inc. Provides Business Update and Announces Second Quarter 2020 Results

- Initiates Phase 1b/2a clinical trial with a proprietary long-acting GLP-1 agonist, in short bowel syndrome; first patients dosed in July and top-line data expected by Q1 2021 -
- Amended definition of primary endpoint for Phase 3 trial with larazotide in celiac disease, allowing reduction in participants from 630 to 525 while maintaining statistical powering at 90% -
- Multiple inflection points and catalysts anticipated over next 18 months-

Raleigh, NC, August 12, 2020 - 9 Meters Biopharma, Inc. (Nasdaq: NMTR), a clinical-stage rare and unmet needs-focused gastroenterology company, today announced second quarter financial results for the second quarter ended June 30, 2020 and summarized recent clinical and corporate developments.

John Temperato, President & CEO of 9 Meters Biopharma, commented:
Our advancements at both the corporate and clinical level in the last quarter have been tremendous and I'm very proud of the team's accomplishments, as we have now assembled multiple assets from several companies into one corporate entity focused on rare and unmet needs-focused gastroenterology.

Second Quarter Clinical Advancements

Proprietary long-acting GLP-1 agonist for short bowel syndrome

- Initiated Phase 1b/2a clinical trial in SBS (June 2020)
 - First patients dosed in July
 - Top-line data expected by Q1 2021
- Anticipate a timely study completion with single-center involvement if no new or unexpected disruption from COVID-19

Larazotide for celiac disease

- Amended Definition of Primary Endpoint for Phase 3 Trial in Celiac Disease After Consultation with FDA (June 2020)
 - Revised analytical approach to primary efficacy outcome allows reduction in participants from 630 to 525 while maintaining statistical powering at 90%
 - Continuous variable approach instead of responder analysis more aptly reflects change in celiac disease patient symptoms over trial duration
- Granted thorough QT Study Waiver by FDA for Larazotide Being Studied for Celiac Disease (May 2020)
- Despite headwinds due to the COVID-19 pandemic and restrictions from state closures, our clinical trial sites have increased to 115 in the last quarter
- Three abstracts presented at DDW pertaining to larazotide's MoA and activity in vivo in multiple models
- Announced Issuance of Patent for Use of Larazotide in Acute Lung Injury (ALI) and Acute Respiratory Distress Syndrome (ARDS) (July 2020)

Proprietary long-acting, GLP-2

- Advanced process to identify an appropriate rare, unmet GI indication selection NM-004
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- Generated regulatory approach to a pediatric UC indication and potential other rare and unmet GI indications

Assembled a Scientific Advisory Board consisting of six leading experts in the gastroenterology field .

Mr. Temperato further noted, "in the second quarter of 2020 9 Meters significantly advanced its clinical initiatives while effectively integrating the three companies that formed 9 Meters. We continue to raise the visibility of the company in the capital markets as we progress towards our upcoming clinical milestones and look forward to sharing results with investors as soon as it is available."

Anticipated Milestones through 2020 & 2021

- Long Acting GLP-1 agonist for Short Bowel Syndrome
Topline data **Q1 2021**
- Larazotide for Celiac Disease
Statistical sizing interim analysis planned mid-2021
Topline readout Phase 3 study by end of **2021**
- NM-003 - Long Acting GLP-2
Lead indication selection **2H 2020**
- NM-004 - Immunomodulator
Lead indication selection **2H 2020**
- Continue to pursue strategic in-licensing & out-licensing opportunities
- Execution of publication strategy on key data readouts

Second Quarter Financial Results

The Company reported a net loss of approximately \$44.6 million, or \$0.57 per share, for the second quarter of 2020, compared to a net loss of approximately \$4.5 million, or \$0.13 per share, for the second quarter of 2019. The June 2020 results include approximately \$41.4 million of charges related to the Company's recent mergers.

As of June 30, 2020, the Company's cash and cash equivalents and marketable securities totaled approximately \$13.5 million, compared to approximately \$2.7 million on March 31, 2020.

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 involve risks and uncertainties, and include, but are not limited to, the potential effects of the ongoing coronavirus outbreak and related mitigation efforts on the Company's clinical, financial and operational activities; the Company's continued listing on NASDAQ; expectations regarding future financings; the future operations of the Company; the nature, strategy and focus of the

Company; the development and commercial potential and potential benefits of any product candidates of the Company; anticipated preclinical and clinical drug development activities and related timelines, including the expected timing for data and other clinical and preclinical results; the Company having sufficient resources to advance its pipeline; and any other statements that are not historical fact. 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 proposed merger and future financings and (vi) risks associated with the possible failure to realize certain anticipated benefits of the Company's recent merger and the Naia acquisition, 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, 2019, Form 10-Q for the quarter ended March 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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