

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): March 20, 2020

Innovate Biopharmaceuticals, 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	INNT	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 x

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. x

**Item 7.01. Regulation FD Disclosure.**

On March 20, 2020, Innovate Biopharmaceuticals, Inc. (the "Company") issued a press release announcing 2019 financial results and strategic and operational updates. 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.

This Section 7.01 of this Form 8-K and Exhibit 99.1 are each being furnished to the Securities and Exchange Commission (the "SEC") pursuant to Item 7.01 of Form 8-K and are therefore not to be considered "filed" with the SEC.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
Exhibit 99.1	<a href="#">Press release dated March 20, 2020.</a>

**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.

Innovate Biopharmaceuticals, Inc.

Date: March 23, 2020

By: /s/ Edward J. Sitar

Edward J. Sitar

Chief Financial Officer

# Innovate Biopharmaceuticals Announces Full Year 2019 Financial Results And Strategic And Operational Updates

RALEIGH, N.C., March 20, 2020 (GLOBE NEWSWIRE) -- [Innovate Biopharmaceuticals, Inc.](#) (the “Company” or “Innovate”) (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel autoimmune and inflammation therapeutics, announced that it has filed its 2019 Annual Report on Form 10-K today.

## RECENT STRATEGIC AND OPERATIONAL HIGHLIGHTS

- The closing of merger with RDD Pharma Ltd. is expected around the end of the first quarter/beginning of the second quarter of 2020. The merged company renamed 9 Meters Biopharma, Inc., will create a platform company focusing on rare, orphan, and unmet needs in gastrointestinal disorders.
- The Phase 3 clinical trial for celiac disease continues with about 100 active clinical trial sites. A top-line readout for the trial is anticipated in 2021. The Company continues to monitor the evolving situation with COVID-19, which could directly or indirectly impact the clinical trial in several ways including pace of enrollment, regulatory interactions and trial operations over the next several months.
- On March 20, 2020 the Company extended its tender offer for most of the outstanding warrants through the earlier of the closing of the RDD merger or April 20, 2020 and adjusted the exercise price to \$0.10 per warrant.

“During 2019 we made a decision to transform the business significantly and we continue to work diligently to complete the merger” stated Sandeep Laumas, M.D., Executive Chairman, of Innovate. Dr. Laumas further said, “The combined company, 9 Meters Biopharma, Inc., will include a diversified pipeline of novel compounds and active clinical studies. We are moving forward with a mission to treat a broad array of rare and orphan diseases. While the COVID-19 pandemic may affect the timing of the transaction and our clinical trial, we continue to move forward with the merger process.”

## FULL YEAR 2019 FINANCIAL RESULTS

Total operating expenses for full year 2019 were \$25.5 million as compared to \$18.2 million for full year 2018, a 40% increase. Cash and cash equivalents totaled \$4.6 million as of December 31, 2019. For more information please see Innovate's Annual Report on Form 10-K for the year ended December 31, 2019.

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**About Innovate Biopharmaceuticals, Inc. (Nasdaq:INNT):**

Innovate is a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases. Innovate's lead drug candidate, larazotide acetate, has a mechanism of action that renormalizes the dysfunctional intestinal barrier by decreasing intestinal permeability and reducing antigen trafficking, such as gliadin fragments in celiac disease, and bacterial toxins and immunogenic antigens in nonalcoholic steatohepatitis (NASH). In several diseases, including celiac disease, NASH, ASH, Crohn's disease, ulcerative colitis, irritable bowel syndrome (IBS), type 1 diabetes mellitus (T1DM), chronic kidney disease (CKD), the intestinal barrier is dysfunctional with increased permeability. On October 7, 2019, the Company announced that it had entered into a definitive merger agreement pursuant to which the Company agreed to acquire all of the outstanding capital stock of privately held RDD in an all-stock transaction. This transaction includes a concurrent capital raise led by OrbiMed Advisors LLC. After closing the Company plans to change its name to 9 Meters Biopharma. The transaction is expected to close around the end of the first quarter/beginning of the second quarter of 2020, subject to the completion of the remaining closing conditions and receipt of regulatory approval in Israel.

For more information, please visit [www.innovatebiopharma.com](http://www.innovatebiopharma.com).

## **Forward Looking Statements**

This press release includes forward-looking statements based upon Innovate's and RDD's current expectations. Forward-looking statements involve risks and uncertainties, and include, but are not limited to, statements about the structure, timing and completion of the proposed Merger; statements about the expected timing of regulatory approvals, the potential effects of the ongoing coronavirus outbreak and related mitigation efforts on both the timing of the Merger closing and concurrent financing and the company's clinical activities, the combined company's listing on Nasdaq after closing of the proposed Merger; expectations regarding the ownership structure of the combined company; the expected executive officers and directors of the combined company; the combined company's expected cash position at the closing of the proposed Merger; expectations regarding the financing; the future operations of the combined company; the nature, strategy and focus of the combined company; the development and commercial potential and potential benefits of any product candidates of the combined company; the executive and board structure of the combined company; the location of the combined company's corporate headquarters; 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 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) the risk that the conditions to the closing of the proposed Merger are not satisfied; (ii) uncertainties as to the timing of the consummation of the proposed Merger and the ability of each of Innovate and RDD to consummate the proposed Merger; (iii) risks related to Innovate's ability to manage its operating expenses and its expenses associated with the proposed Merger pending closing; (iv) risks related to the failure or delay in obtaining required approvals from any governmental or quasi-governmental entity necessary to consummate the proposed Merger; (v) the risk that as a result of adjustments to the exchange ratio, Innovate stockholders and RDD stockholders could own more or less of the combined company than is currently anticipated; (vi) risks related to the market price of Innovate common stock relative to

the exchange ratio; (vii) unexpected costs, charges or expenses resulting from the transaction; (viii) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed Merger; (ix) the uncertainties associated with the clinical development and regulatory approval of product candidates; (x) risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance these product candidates and its preclinical programs; (xi) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (xii) 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; (xiii) the the impact of COVID-19 on our operations, clinical trials or proposed merger and future financings and (xiiii) risks associated with the possible failure to realize certain anticipated benefits of the proposed Merger, 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 as a result 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 Innovate's Annual Report on Form 10-K for the year ended December 31, 2019 and in other filings that Innovate has made and 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. Innovate 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.

Jennifer K. Zimmons, Ph.D.

Investor Relations

Tel: +1-917-214-3514

Email: [jjimmons@innovatebiopharma.com](mailto:jjimmons@innovatebiopharma.com)

[www.innovatebiopharma.com](http://www.innovatebiopharma.com)

**SOURCE:** Innovate Biopharmaceuticals, Inc.