

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 17, 2019

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))

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.

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## **Item 2.02. Results of Operations and Financial Condition.**

On March 19, 2019, Innovate Biopharmaceuticals, Inc. (the “Company”) issued a press release regarding its financial results for the fourth quarter and year ended December 31, 2018 and recent corporate developments. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated into this Item 2.02 by reference.

The information in this Current Report on Form 8-K furnished pursuant to Item 2.02, including Exhibit 99.1, shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liability under that section, and they shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

## **Item 3.02. Unregistered Sales of Equity Securities.**

On March 17, 2019, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with SDS Capital Partners II, LLC and certain other accredited investors (each, a “Purchaser” and together, the “Purchasers”) pursuant to which it sold, on March 18, 2019, 4,181,068 shares (the “Shares”) of its common stock, par value \$0.0001 per share (the “Common Stock”) and issued short-term warrants (the “Short-Term Warrants”) to purchase up to 4,181,068 shares of Common Stock and long-term warrants (the “Long-Term Warrants”) and, together with the Short-Term Warrants, the “Warrants”) to purchase up to 2,508,634 shares of Common Stock. Pursuant to the Purchase Agreement, the Company issued the Shares and the Warrants at a purchase price per share of \$2.33 for aggregate gross proceeds of approximately \$9.7 million. The Shares were registered on the Company’s Registration Statement on Form S-3, File No. 333-223669, and the Warrants were issued pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder, to the accredited investor Purchasers.

The Long-Term Warrants are exercisable for five years beginning on the on the six-month anniversary of the date of issuance. The Long-Term Warrants have an initial exercise price equal to \$2.56, subject to certain adjustments. The Short-Term Warrants are exercisable immediately upon the date of issuance for a period of one year. The Short-Term Warrants have an initial exercise price of \$4.00 per share, subject to certain adjustments. If at any time commencing on the date of issuance, the weighted-average price of the Common Stock exceeds \$5.25 for ten consecutive trading days, the Company may call the outstanding Short-Term Warrants and require that they be exercised in cash, except to the extent that such exercise would surpass the beneficial ownership limitation described below for such warrant’s holder. If not previously exercised in full, at the expiration of their applicable terms, the Warrants shall be automatically exercised via cashless exercise.

The Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to the Company a duly executed exercise notice and by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not then effective or available, the holder may exercise the Warrant through a cashless exercise, in whole or in part, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the Warrant. No fractional shares of common stock will be issued in connection with the exercise of a Warrant. In lieu of fractional shares, the Company will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

A holder will not have the right to exercise any portion of the Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to the Company, provided that any increase in such percentage shall not be effective until 61 days after such notice.

In the event of a fundamental transaction, as described in the Warrants and generally including any reorganization, recapitalization or reclassification of the Common Stock, the sale, transfer or other disposition of all or substantially all of the Company’s properties or assets, the consolidation or merger of the Company with or into another person, the holders of the Warrants will be entitled to receive upon exercise of the Warrants the kind and amount of securities, cash or other property that the holders

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would have received had they exercised the Warrants immediately prior to such fundamental transaction. In addition, upon a fundamental transaction, the holder shall have the right to receive a payment in cash, or under certain circumstances in other consideration, from the Company at the Black Scholes value as described in the Warrants.

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

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
Exhibit 99.1	<a href="#">Press release issued March 19, 2019</a>

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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.

Innovate Biopharmaceuticals, Inc.

Date: March 19, 2019

By: /s/ Jay P. Madan

Jay P. Madan

President and Chief Business Officer

## Innovate Biopharmaceuticals Reports Financing to Initiate the First Phase 3 Clinical Trial in Celiac Disease, Fiscal Year 2018 Earnings and Key Corporate Highlights

*Innovate closes an equity financing with gross proceeds of \$9.7 million*

*Continued launch activities for start of the first Phase 3 celiac disease trial, expected to start Q2 2019*

*Continued research collaborations studying new indications for larazotide: known mechanism of action involving benefits of reducing intestinal permeability*

RALEIGH, N.C., March 19, 2019, Innovate Biopharmaceuticals, Inc. (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, announced today that on March 18, 2019, it closed its previously announced equity financing, resulting in gross proceeds of \$9.7 million. The Company expects to use the estimated net proceeds of approximately \$9.6 million from the offering to initiate its first Phase 3 registration trial of larazotide acetate, or INN-202, for celiac disease, and for working capital and general corporate purposes. On March 18, 2019, the Company also reported its year end 2018 financial results and key highlights.

### Recent Achievements and Upcoming Milestones

#### *Clinical*

- Innovate entered into an agreement with ICON Clinical Research Limited to facilitate the Company's completion of startup activities required to initiate its Phase 3 clinical trial for celiac disease.
- Manufacturing of the drug product for our Phase 3 trial has been completed.

#### *R&D*

- Acceptance of three abstracts to the 2019 Digestive Disease Week (DDW) through collaboration with North Carolina State University and Massachusetts General Hospital, including one with Prof. Anthony Blikslager of North Carolina State University to understand the molecular biology and mechanism of action of larazotide.

#### *Upcoming Milestones*

- Start of the first Phase 3 celiac disease trial
- Continuation of pre-clinical studies for non-alcoholic steatohepatitis (NASH) and alcoholic steatohepatitis (ASH).
- Initiation of additional scientific and clinical collaborations.

Sandeep Laumas, M.D., CEO of Innovate, said, "The fourth quarter of 2018 was focused on continued preparation for our first celiac disease phase 3 clinical trial, which we plan to initiate in the second quarter of 2019. We are also encouraged by the pre-clinical data we have seen for NASH so far, and Innovate intends to continue further pre-clinical work for the use of larazotide in the treatment of NASH."

### 2018 Financial Results

Net loss for the year ended December 31, 2018, was \$24.2 million, or \$(0.98) per basic and diluted share, compared to net loss of \$11.6 million, or \$(0.98) per basic and diluted share for the same period ended December 31, 2017.

Research and development expenses were \$7.6 million for the year ended December 31, 2018, an increase of \$3.6 million, compared to \$4.0 million for the same period ended December 31, 2017, primarily due to an increase in costs associated with the preparation for our Phase 3 clinical trials of INN-202 for celiac disease and an increase in compensation costs related to an increase in research and development personnel.

General and administrative expenses were \$10.7 million for the year ended December 31, 2018, an increase of \$3.5 million, compared to \$7.2 million for the same period ended December 31, 2017, primarily due to an increase in

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compensation costs for general and administrative personnel, an increase in accounting, legal and transaction advisory fees associated with our reverse merger, SEC filings and outsourced accounting personnel as well as an increase in costs associated with operating as a public company. The increase in these costs was partially offset by a decrease in non-cash stock compensation expense.

At December 31, 2018, Innovate had \$5.7 million in cash and cash equivalents compared to \$0.4 million at December 31, 2017.

### **Webcast**

As previously announced, Innovate plans to host an earnings conference call at 8:00 am ET today, March 19, 2019, to discuss its financial results for the fourth quarter and full year ended December 31, 2018, and to provide corporate and operational progress updates. Please visit the Investor section of Innovate's website for further details on accessing the webcast.

A live and archived audio webcast of the conference call will be available on the Events and Presentations page of Innovate's corporate website at [www.innovatebiopharma.com](http://www.innovatebiopharma.com).

### **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, 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.

### **Forward Looking Statements**

This press release includes forward-looking statements including, but not limited to, statements related to the development of drug candidates, our operations and business strategy, capital raising, our expected financial results, and corporate updates. The forward-looking statements contained in this press release are based on management's current expectations and are subject to substantial risks, uncertainty and changes in circumstances. Actual results may differ materially from those expressed by these expectations due to risks and uncertainties, including, among others, those related to our ability to obtain additional capital on favorable terms to us, or at all, including, without limitation, to fund our current and future preclinical studies and clinical trials, including, without limitation, raising additional funds for our Phase 3 registration trial for INN-202, and the success, timing and cost of our drug development program and our ongoing or future preclinical studies and clinical trials, including, without limitation, the possibility of unfavorable new clinical and preclinical data and additional analyses of existing data, as well as the risks that prior clinical and preclinical results may not be replicated. These risks and uncertainties include, but may not be limited to, those described in our Annual Report on Form 10-K filed with the SEC on March 18, 2019, and in any subsequent filings with the SEC. Forward-looking statements speak only as of the date of this press release, and we undertake no obligation to review or update any forward-looking statement except as may be required by applicable law.

SOURCE: Innovate Biopharmaceuticals, Inc.

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