

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): November 13, 2018

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.

Item 2.02. Results of Operations and Financial Condition.

On November 13, 2018, Innovate Biopharmaceuticals, Inc. issued a press release announcing its results of operations for the third quarter ended September 30, 2018. A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated by reference into this report.

This information shall not be deemed to be “filed” for 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, and is not incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
Exhibit 99.1	Press release dated November 13, 2018.

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: November 13, 2018

By: /s/ Jay P. Madan

Jay P. Madan

President and Chief Business Officer



Innovate Biopharmaceuticals Reports Third Quarter 2018 Earnings and Key Corporate Highlights

- *Poster presentation at the American Association of Study of Liver Diseases showing promising pre-clinical data of larazotide acetate in NASH reducing intestinal permeability. Innovate plans to initiate a Phase 2 clinical trial for NASH in 2019*
- *Continued startup activities for launch of the first Phase 3 celiac disease trial which is targeted in the first half of 2019*
- *Continued research collaborations studying new indications for larazotide, which have known mechanism of action involving benefits of reducing permeability and large markets with unmet needs*

RALEIGH, N.C., November 13, 2018-Innovate Biopharmaceuticals, Inc. (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, today reported its third quarter 2018 financial results and key highlights.

Recent Achievements and Upcoming Milestones

Upcoming Milestones

- Continuation of pre-clinical studies for non-alcoholic steatohepatitis (NASH).
- Initiation of additional NASH collaboration.

Clinical

- Innovate entered into an agreement with Amarex Clinical Research for data management and biostatistics for Innovate's planned Phase 3 celiac disease trial.
- Phase 3 celiac disease trial startup preparations continuing with start planned in the first half of 2019.
- Over 150 clinical sites have been identified for the planned Phase 3 celiac disease trial with positive feedback from sites to enroll the first Phase 3 celiac disease trial.
- Clinical trial material for Phase 3 is currently being manufactured.

Research

- Presented poster in collaboration with Sanyal Biotechnology at The Liver Meeting® 2018, the annual meeting of the American Association for the Study of Liver Diseases (AASLD) in November 2018. The data showed larazotide was effective in restoring gut permeability in a NASH pre-clinical model. (see press release from November 12, 2018)
- Continued collaboration with Anthony Blikslager, DVM, PhD, DACVS, AGAF, of North Carolina State University to understand and characterize the mechanism of action.
- Continued collaboration with James Nataro, MD, PhD, MBA, of the University of Virginia to study larazotide's effect on improving the microbiome of children with environmental enteric dysfunction (EED). (see press release from July 31, 2018)

Christopher Prior, Ph.D., CEO of Innovate, said, "The third quarter of 2018 was focused on continued preparation for initiation of the first Phase 3 clinical trial planned for the first half of 2019. With very encouraging pre-clinical data for NASH, Innovate will continue further pre-clinical work and target the initiation of a Phase 2 NASH clinical trial in 2019. We continue to forge our collaborations to further enrich our pipeline."

Third Quarter 2018 Financial Results

Net loss for the three months ended September 30, 2018, was \$0.8 million, or \$(0.03) per basic and diluted share, compared to net loss of \$2.5 million, or \$(0.08) per basic and diluted share for the same period ended September 30, 2017.

Research and development expenses were \$(1.8) million for the three months ended September 30, 2018, a decrease of \$2.2 million, compared to \$0.4 million for the same period ended September 30, 2017 primarily due to a re-measurement of stock option compensation expense related to a decline in our stock price from June 30, 2018 to September 30, 2018.

General and administrative expenses were \$1.6 million for the three months ended September 30, 2018, a decrease of \$0.4 million, compared to \$2.0 million for the same period ended September 30, 2017 primarily due to a re-measurement of stock option compensation expense related to a decline in our stock price from June 30, 2018 to September 30, 2018.

At September 30, 2018, Innovate had \$8.1 million in cash and cash equivalents, compared to \$10.7 million at June 30, 2018 and \$0.4 million at December 31, 2017.

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.

In celiac disease, larazotide is the only drug which has successfully met its primary endpoint with statistical significance in a Phase 2b efficacy clinical trial (342 patients). Innovate completed the End of Phase 2 Meeting with the FDA in 2017 and is preparing to begin Phase 3 registration clinical trials for celiac disease, targeted to commence in the first half of 2019. Nearly 600 subjects have been exposed to larazotide in clinical trials, and a safety profile comparable to placebo has been demonstrated. Larazotide has received Fast Track designation from the FDA for celiac disease.

Forward Looking Statements

This press release includes forward-looking statements including, but not limited to, statements related to the potential for Innovate's drug development pipeline candidates in treating the diseases and conditions for which they are being developed, Innovate's start of clinical trials for celiac disease, NASH, Crohn's disease, and ulcerative colitis, and Innovate's ability to develop future collaborations. 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; the success, timing and cost of our drug development program and our ongoing or future 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; the lengthy and unpredictable nature of the drug approval process; and our ability to commercialize our product candidates if approved. These risks and uncertainties include, but may not be limited to, those described in our Quarterly Report on Form 10-Q filed with the SEC on November 13, 2018, 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.

Innovate Biopharmaceuticals, Inc.

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