

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 15, 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 7.01. Regulation FD Disclosure.

On August 15, 2018, Innovate Biopharmaceuticals, Inc. issued a press release announcing its results of operations for the second quarter ended June 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 August 15, 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: August 15, 2018

By: /s/ Jay P. Madan

Jay P. Madan

President and Chief Business Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated August 15, 2018.



Innovate Biopharmaceuticals Reports Second Quarter 2018 Earnings and Key Corporate Highlights

- *Added as a member of the broad-market Russell 3000®*, *2000®* and *Microcap®* *Indexes*
- *Innovate plans to host a Clinical and Scientific Update on September 6, 2018, in New York City*
- *Multiple research collaborations with academic partners for potential new indications*

RALEIGH, N.C., August 15, 2018-Innovate Biopharmaceuticals, Inc. (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, today reported its second quarter 2018 financial results and key highlights.

Recent Achievements and Upcoming Milestones

Upcoming Milestones

- Phase 3 celiac disease trial startup preparations underway with clinical site evaluations and patient dosing targeted before year end
- Pre-clinical studies for non-alcoholic steatohepatitis (NASH) expected to readout in late Q3
- Innovate plans to host a *Clinical and Scientific Update* on Thursday, September 6, 2018, from 8:15am-11:00am at the Omni Hotel (52nd St. & Madison Ave.) in New York City

Corporate

- Innovate Biopharmaceuticals Inc. was added as a member of the broad-market Russell 3000®, 2000® and Microcap® Indexes effective June 25, 2018, as part of the 2018 Russell indexes reconstitution
- Innovate intends to present at the 20th Annual Rodman & Renshaw Global Investment Conference on September 5, 2018, at 12:05pm at the St. Regis in New York City

Research

- Presented two posters in collaboration with North Carolina State University at the Digestive Disease Week medical conference 2018 highlighting larazotide's novel mechanism of action and pharmacology
- Continued collaboration with Anthony Blikslager, DVM, PhD, DACVS, AGAF, of NC State to understand and characterize the mechanism of action and dose response of larazotide
- Initiated collaboration with O. Colin Stine, PhD, of the University of Maryland, Baltimore to study larazotide's corrective effect on the dysfunctional intestinal barrier and the dysfunctional microbiome (see press release from June 28, 2018)
- Initiated collaboration with James Nataro, MD, PhD, MBA, of 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 second quarter of 2018 marked continued progress for Innovate as we continued to advance the startup activities for our celiac disease Phase 3 trials and progress our NASH program. We are also excited about our ongoing and new research collaborations with various partners to leverage our mechanism of action to address unmet medical needs."

Second Quarter 2018 Financial Results

Net loss for the three months ended June 30, 2018, was \$4.2 million, or \$(0.16) per basic and diluted share, compared to net loss of \$2.8 million, or \$(0.23) per basic and diluted share for the same period ended June 30, 2017.

Research and development expenses were \$1.2 million for the three months ended June 30, 2018, an increase of \$0.1 million, compared to \$1.1 million for the same period ended June 30, 2017.

General and administrative expenses were \$2.1 million for the three months ended June 30, 2018, an increase of \$0.6 million, compared to \$1.5 million for the same period ended June 30, 2017.

At June 30, 2018, Innovate had \$10.7 million in cash and cash equivalents, compared to \$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 successfully 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 later in 2018. Larazotide has been exposed to more than 800 subjects in clinical trials demonstrating a favorable safety profile comparable to placebo for long-term chronic administration. 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, the success, timing and cost of our drug development program and our ongoing or future clinical trials, 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 August 14, 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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www.innovatebiopharma.com