

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 8, 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))

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

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 8, 2019, Innovate Biopharmaceuticals, Inc. (the “Company”) issued a press release with second quarter 2019 results and corporate 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.

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
Exhibit 99.1	Press release dated August 8, 2019.

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 8, 2019

By: /s/ Edward J. Sitar

Edward J. Sitar

Chief Financial Officer



Innovate Biopharmaceuticals Reports Second Quarter 2019 Results and Corporate Updates

Company is exploring potential strategic opportunities and non-dilutive sources of capital and partnerships

Continued activities of the first Phase 3 clinical trial for celiac disease including the screening and monitoring of potential subjects

RALEIGH, N.C., Aug. 8, 2019 (GLOBE NEWSWIRE) -- 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 2019 financial results and corporate updates.

Recent Developments

Clinical

- The screening and monitoring of patients in the first Phase 3 celiac disease trial continues
- Company has secured an initial set of 17 active clinical testing sites

Research and development

- Research collaboration with Institut Gustave Roussy continues to study regulation of intestinal permeability and the gut microbiota using larazotide in immuno-oncology checkpoint inhibitor failure preclinical models
- Data analysis from pre-clinical models in NASH advances from studying larazotide in both *ex vivo* and animal models
- Progression of research collaboration with Dr. Jay Luther and Dr. Raymond Chung at the Gastroenterology Division at Massachusetts General Hospital to research the effects of larazotide on certain forms of alcoholic liver disease, such as ASH
- Presented 3 posters at DDW 2019 in May
- Acceptance of poster at 2019 World Congress of Gastroenterology in September

Second Quarter 2019 Financial Results

Net loss for the three months ended June 30, 2019 was \$4.5 million or \$0.13 per share. Research and development expenses were \$3.1 million and general and administrative expenses were \$3.0 million for the three months ended June 30, 2019, respectively. Cash and cash equivalents were \$13.3 million at June 30, 2019, compared to \$5.7 million at December 31, 2018.

Sandeep Laumas, M.D., Innovate's Executive Chairman and Chief Executive Officer, noted, "The second quarter of 2019 was focused on the start of the first Phase 3 clinical trial for celiac disease. Given the nature of celiac disease, the design of our screening and enrollment procedures are particular. We look forward to continuing to update our investors on our progress." Dr. Laumas continued, "The board and management of Innovate strongly believe that our novel therapeutics have significant clinical and economic potential in providing treatment where none exists. We are excited for the progress of the Phase 3 trial for celiac disease and expect to continue to explore various potential non-dilutive financing options and other strategic opportunities that we believe could bring value to our stockholders."

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 succession planning and our management team, 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 identify, recruit and retain key talent, 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 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, uncertainties with respect to evaluating strategic options and completing strategic transactions, 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 Form 10-K for the year ended December 31, 2018, our Form 10-Q for the quarter ended June 30, 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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