

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): June 10, 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 8.01. Other Events.

On June 10, 2019, Innovate Biopharmaceuticals, Inc. (the "Company") issued a press release with an update on starting the first ever Phase III Clinical Trial in Celiac Disease. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
Exhibit 99.1	Press release dated June 10, 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: June 10, 2019

By: /s/ Jay P. Madan

Jay P. Madan

President and Chief Business Officer



Innovate Biopharmaceuticals Announces the Start of the First Phase 3 Clinical Trial in Celiac Disease

Launch of the first ever phase 3 trial in the history of celiac disease

RALEIGH, N.C., June 10, 2019, Innovate Biopharmaceuticals, Inc. (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, announced the start of the first phase 3 clinical trial in celiac disease. Innovate expects to provide further updates as screening and enrollment proceed over the next few months.

Innovate's Chief Medical Officer, Dr. Patrick H. Griffin, stated, "We are proud to start the first ever phase 3 clinical trial to address a large unmet need for celiac patient suffering from continued symptoms in spite of being on a gluten-free diet." Innovate's Chairman and CEO, Dr. Sandeep Laumas, added, "This is a landmark event in the history of celiac disease for the first ever phase 3 trial to get underway as well as a key pivotal moment for Innovate. We are especially thankful to our partners, physicians and our investors whose support of Innovate's management has led to this outcome."

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 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 Quarterly Report on Form 10-Q filed with the SEC on May 10, 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.

Contact:

Jennifer K. Zimmons, Ph.D.
Investor Relations

Tel: +1-917-214-3514

Email: jzimmmons@innovatebiopharma.com

www.innovatebiopharma.com