

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 20, 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.

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**Item 1.01. Entry into a Material Definitive Agreement.**

On August 20, 2018, Innovate Biopharmaceuticals, Inc. ("Innovate") entered into a Master Services Agreement (the "Agreement") with Amarex Clinical Research, LLC ("Amarex") pursuant to which Innovate may engage Amarex to provide electronic data capture solutions and associated services for data management, biostatistics and safety monitoring for clinical trials pursuant to project work orders mutually agreed between the parties. The Agreement and any project work orders thereunder may be terminated by Innovate at any time upon 30 days' written notice to Amarex. In addition, either party may terminate the Agreement or any project work orders thereunder upon 30 days' written notice (with the opportunity to cure) in the event of a material default in performance by the other party or immediately in the event of any bankruptcy, insolvency, liquidation or assignment for the benefit of creditors of the other party.

The foregoing description of the Agreement is a summary, is not complete and is qualified in its entirety by reference to the actual Agreement, which will be filed as an exhibit to Innovate's Quarterly Report on Form 10-Q for the quarter ending September 30, 2018, portions of which will be subject to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

**Item 7.01. Other Events.**

On August 23, 2018, Innovate issued a press release announcing the entry into the Agreement by Innovate and Amarex. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report. The information in Item 7.01 of this Current Report, including the attached Exhibit 99.1 furnished herewith, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the [Securities Exchange Act of 1934, as amended (the "Exchange Act")/Exchange Act], or otherwise subject to the liabilities of that Section. The information in Item 7.01 of this Current Report, including Exhibit 99.1, shall not be deemed 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 to this Current Report in such a filing.

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

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
Exhibit 99.1	Press release dated August 23, 2018.

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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: August 23, 2018

By: /s/ Jay P. Madan

Jay P. Madan

President and Chief Business Officer

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**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release dated August 23, 2018.</a>



## **Innovate Biopharmaceuticals Enters into an Agreement with Amarex Clinical Research for Data Management and Biostatistics for Phase 3 Celiac Disease Trial**

RALEIGH, N.C., August 23, 2018-Innovate Biopharmaceuticals, Inc. (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, today announced it signed an agreement with Amarex Clinical Research to provide data management and biostatistics for its planned Phase 3 celiac disease trial. Pursuant to the agreement, Amarex will provide Innovate with electronic data capture solutions and associated services for data management and biostatistics.

June Almenoff, M.D., Ph.D., F.A.C.P, CMO and COO of Innovate said, “With their strong expertise in biostatistics and data management, I am pleased to be working with Amarex to support our Phase 3 trial. Our clinical team has been impressed with Amarex’s capabilities, and we look forward to a productive working relationship.”

Kazem Kazempour, Ph.D., Amarex’s President and Chief Executive Officer, said, “We are excited to support Innovate in the development of its novel therapeutic, which has the potential to help so many patients suffering from celiac disease. We look forward to working closely with Innovate’s experienced team to advance the clinical development of larazotide for this underserved population.”

### **About larazotide acetate for celiac disease**

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 later in 2018. 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.

### **About Amarex Clinical Research LLC:**

Amarex is a global contract research organization providing clinical trial services to pharmaceutical companies and has expertise in product development plan creation, product safety and efficacy testing, and applications to the FDA for marketing approval of new or improved medical products.

### **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.

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### **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.**

Kendyle Woodard

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