



Innovate Biopharmaceuticals Reports Financing to Initiate the First Phase 3 Clinical Trial in Celiac Disease, Fiscal Year 2018 Earnings and Key Corporate Highlights

March 19, 2019

Innovate closes an equity financing with gross proceeds of \$9.7 million

Continued launch activities for start of the first Phase 3 celiac disease trial, expected to start Q2 2019

Continued research collaborations studying new indications for larazotide: known mechanism of action involving benefits of reducing intestinal permeability

RALEIGH, N.C., March 19, 2019 (GLOBE NEWSWIRE) -- Innovate Biopharmaceuticals, Inc. (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, announced today that on March 18, 2019, it closed its previously announced equity financing, resulting in gross proceeds of \$9.7 million. The Company expects to use the estimated net proceeds of approximately \$9.6 million from the offering to initiate its first Phase 3 registration trial of larazotide acetate, or INN-202, for celiac disease, and for working capital and general corporate purposes. On March 18, 2019, the Company also reported its year end 2018 financial results and key highlights.

Recent Achievements and Upcoming Milestones

Clinical

- Innovate entered into an agreement with ICON Clinical Research Limited to facilitate the Company's completion of startup activities required to initiate its Phase 3 clinical trial for celiac disease.
- Manufacturing of the drug product for our Phase 3 trial has been completed.

R&D

- Acceptance of three abstracts to the 2019 Digestive Disease Week (DDW) through collaboration with North Carolina State University and Massachusetts General Hospital, including one with Prof. Anthony Bliklager of North Carolina State University to understand the molecular biology and mechanism of action of larazotide.

Upcoming Milestones

- Start of the first Phase 3 celiac disease trial
- Continuation of pre-clinical studies for non-alcoholic steatohepatitis (NASH) and alcoholic steatohepatitis (ASH).
- Initiation of additional scientific and clinical collaborations.

Sandeep Laumas, M.D., CEO of Innovate, said, "The fourth quarter of 2018 was focused on continued preparation for our first celiac disease phase 3 clinical trial, which we plan to initiate in the second quarter of 2019. We are also encouraged by the pre-clinical data we have seen for NASH so far and Innovate intends to continue further pre-clinical work for the use of larazotide in the treatment of NASH."

2018 Financial Results

Net loss for the year ended December 31, 2018, was \$24.2 million, or \$(0.98) per basic and diluted share, compared to net loss of \$11.6 million, or \$(0.98) per basic and diluted share for the same period ended December 31, 2017.

Research and development expenses were \$7.6 million for the year ended December 31, 2018, an increase of \$3.6 million, compared to \$4.0 million for the same period ended December 31, 2017, primarily due to an increase in costs associated with the preparation for our Phase 3 clinical trials of INN-202 for celiac disease and an increase in compensation costs related to an increase in research and development personnel.

General and administrative expenses were \$10.7 million for the year ended December 31, 2018, an increase of \$3.5 million, compared to \$7.2 million for the same period ended December 31, 2017, primarily due to an increase in compensation costs for general and administrative personnel, an increase in accounting, legal and transaction advisory fees associated with our reverse merger, SEC filings and outsourced accounting personnel as well as an increase in costs associated with operating as a public company. The increase in these costs was partially offset by a decrease in non-cash stock compensation expense.

At December 31, 2018, Innovate had \$5.7 million in cash and cash equivalents compared to \$0.4 million at December 31, 2017.

Webcast

As previously announced, Innovate plans to host an earnings conference call at 8:00 am ET today, March 19, 2019, to discuss its financial results for the fourth quarter and full year ended December 31, 2018, and to provide corporate and operational progress updates. Please visit the [Investor section of Innovate's website](#) for further details on accessing the webcast.

A live and archived audio webcast of the conference call will be available on the Events and Presentations page of Innovate's corporate website at www.innovatebiopharma.com.

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 registration 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 Annual Report on Form 10-K filed with the SEC on March 18, 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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Source: Innovate Biopharmaceuticals, Inc