



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

April 10, 2018

Jay P. Madan  
President  
Innovate Biopharmaceuticals, Inc.  
8480 Honeycutt Road, Suite 120  
Raleigh, North Carolina 27615

**Re: Innovate Biopharmaceuticals, Inc.**  
**Amendment No. 1 to Form 8-K**  
**Filed March 29, 2018**  
**File No. 001-37797**

Dear Mr. Madan:

We have reviewed your filing and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response to these comments, we may have additional comments.

Amendment No. 1 to Form 8-K filed March 29, 2018

Innovate Business, page 4

1. We note your disclosure in several places regarding the "favorable safety profile" of your product candidates. This is a conclusion that is within the FDA's authority. Please remove or revise these statements accordingly.

Our Drug Product Pipeline, page 8

2. Please remove the global market potential column from your product pipeline table. It is inappropriate to include this information in the product pipeline table since you do not have any approved product candidates.

Summary of Key Clinical Trials using Larazotide in Celiac Disease, page 11

3. We note your disclosure that five patients experienced a serious adverse event over the course of seven clinical trials. Please disclose all of the serious adverse events that the five patients experienced.

INN-217: Non-alcoholic steatohepatitis (NASH) and The Microbiome, page 18

4. With respect to the expected size of the market for NASH therapeutics in the major markets, please disclose what portion of this market is attributed to the specific type of product that you intend to provide. Also, please revise your disclosure to indicate whether you intend to serve these major markets here and wherever you provide data concerning the major markets for your product candidates.

INN-108: Mild-to-Moderate Ulcerative Colitis, page 19

5. We note the disclosure that was added in response to prior comment 10. Please disclose the dates that each of the Phase 1 trials was conducted.

Licensing Agreements, page 22

6. We note your response to our prior comment 13 and your disclosure in this section regarding the expiration dates of the last to expire patents. Please specify in this section which patents are the most significant in each patent portfolio.

Asset Purchase Agreement, page 24

7. We note your response to our prior comment 15 and reissue with respect to your asset purchase agreement with Repligen Corporation. Please revise your disclosure to include the royalty rate or royalty range not to exceed a ten percent range.

Unaudited Pro Forma Condensed Combined Financial Information as of and for the Year Ended December 31, 2017

2) Pro Forma Adjustments, page 119

8. We acknowledge your response to our prior comment 23. Noting that you recognized a pro forma Net loss during the year ended December 31, 2017, please amend caption "(h)" to remove mention of "pro forma combined fully diluted shares outstanding", as we do not believe this measure is either relevant or required in your filing.

Unaudited Pro Forma Condensed Combined Financial Information as of and for the Nine Months Ended September 30, 2017, page 120

9. We note you updated your Form 8-K filing to include pro forma financial statements for the year ended December 31, 2017. As such, please remove your pro forma financial statements for the period ended September 30, 2017.

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We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

You may contact Jacob Luxenburg at (202) 551-2339 or Sharon Blume at (202) 551-3474 if you have questions regarding comments on the financial statements and related matters. Please contact Chris Edwards at (202) 551-6761 or Ada Sarmento at (202) 551-3798 with any other questions.

Division of Corporation Finance  
Office of Healthcare & Insurance

cc: Daniel Horwood, Esq.