



DIVISION OF
CORPORATION FINANCE

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

March 2, 2018

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

Re: Innovate Biopharmaceuticals, Inc.
Current Report on Form 8-K
Filed February 2, 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.

Form 8-K Filed on February 2, 2018

Cautionary Statement Concerning Forward-Looking Statements, page 5

1. Please revise the last sentence in this section to clarify that you do not undertake any obligation to publicly update any statements, except as required by applicable law.

Innovate Business, page 6

2. Please disclose all investigational new drug applications (INDs) that have been submitted to the FDA for each applicable product candidate. For any active INDs related to your product candidates, please also disclose when each IND was submitted, the sponsor(s) of the IND and the specific indications listed therein. If you believe that no INDs are required for any of these products and/or indications at this time, please explain why in your disclosure.

3. Please disclose what you mean by "major markets" the first time such term is used.
4. We note your statements that your product candidates have established, proven or solid safety profiles, proven safety and efficacy, demonstrated or established safety and that larazotide is a safe drug. Safety and efficacy determinations are solely within the FDA's authority. As your product candidates have not received FDA approval, it is premature to state that they are safe or effective. Please remove or revise these statements.
5. Please revise your disclosure to explain what you mean by the term "clinically meaningful."
6. We note your statements that larazotide has a first-in-class mechanism of action as a tight junction regulator. These statements imply an expectation of regulatory approval, which is inappropriate given the current stage of development. Please remove these statements from the descriptions of larazotide.

Summary of Key Clinical Trials using Larazotide in Celiac Disease, page 14

7. Please disclose the dates that each of these trials was conducted, who conducted the trials, the serious adverse events that patients experienced in each trial and the number of patients who experienced them.

Clinical Trial ('012) Met the Primary Endpoint with Statistical Significance , page 15

8. We note your statement in this section that you have a wholly-owned and copyrighted primary end point created specifically for celiac disease. Please disclose whether you have registered for copyright protection, and, if so, in which jurisdictions, how long such protection will last and how such registration protects your copyright. Please also disclose why the primary end point is covered by a copyright as opposed to a patent or trademark and the scope of protection that having a copyright provides you if you have not registered your copyright.

Enteropathy-associated T-cell lymphoma (EATL): High Mortality Rate and Unmet Need, page 22

9. Please disclose the sources for the statistics in this section.

INN-108 Clinical Development Pathway, page 26

10. Please disclose when the Phase I trial was conducted, who conducted the trial, the serious adverse events that patients experienced and the number of patients who experienced them.

Ulcerative Colitis: Lack of Innovation in New Drug Development for Past Several Decades, page 26

11. We note your disclosure regarding the launch of the generic Lialda. Please revise this section to disclose what IMS stands for and to provide balancing language that the experience of Lialda is not an indication of a similar result with respect to INN-108.

Innovate's Intellectual Property, page 28

12. We note that your patent families have upcoming expiration dates in 2018. Please discuss whether you expect the expiration of these patents to have a material effect on your business.
13. Please expand your description of your patent portfolios to specifically describe the patent families related to INN-202 and INN-108. Please disclose the type of patent protection you have (such as composition of matter, use or process, etc.) for each product candidate. In addition, please revise to disclose whether you license or own your patents and patent applications relating to INN-202 and INN-108. Please also specify the expiration dates for of the most significant patents within each patent portfolio.

CeD PRO: Copyrighted Primary Endpoint for Celiac Disease Tested in a Successful Clinical Trial, page 29

14. We note your statement in this section that you believe that if larazotide is the first approved drug for celiac disease, the patient reported outcome (PRO) primary end point for celiac disease will become part of the drug label creating another barrier to entry for potential competitors and that any company seeking to develop a drug for celiac disease would either need to develop their own PRO or would be required to license this PRO from Innovate. Please disclose your basis for such belief.

Licensing Agreements, page 29

15. Please revise your description of your licensing agreements with Alba Therapeutics and Seachaid Pharmaceuticals and the asset purchase agreement with Repligen Corporation to provide the following information:
 - the one-time, non-refundable fees payable;
 - aggregate milestones payable; and
 - royalty rate (or royalty range not to exceed a ten percent range).Please file the license agreements and the asset purchase agreement as exhibits or tell us why you believe that you are not required to file such agreements pursuant to Item 601(b)(10) of Regulation S-K.

Risk Factors, page 43

16. Please update your risk factors to reflect that the merger has been completed. For example, we note the language in the first two risk factors on page 72.

We are an “emerging growth company,” and the reduced disclosure requirements..., page 76

17. Based on the disclosure on the cover page, it appears that you have elected to use the transition period for complying with new or revised accounting standards, which is inconsistent with the disclosure in this risk factor that you have elected not to avail yourselves of this exemption. Please advise or revise.

Security Ownership of Certain Beneficial Owners and Management, page 84

18. Please revise your disclosure to identify the natural person or persons, if any, who have voting and investment control of the shares held by BrynMawr Technology Holdings, Moonstar Family Group, The Sea Island Partnership and Triangle Healthcare Partners.

Executive Compensation, page 92

19. Please revise your disclosure to include director and executive compensation for the fiscal year ended December 31, 2017.

Employment and Severance Agreements, page 93

20. We note your disclosure that you have entered into employment agreements with each of your named executive officers. Please file these agreements, and any amendments thereto, as exhibits.

Related Party Transactions, page 98

21. Please disclose the material terms of the outstanding loan to Mr. Madan including the interest rate and repayment terms.

Unaudited Pro Forma Financial Statements for Spin-Co Adjustment, page F-19

22. In your Pro Forma Financial Statements for the Spin-Co adjustment you reference a "Note 4", which would appear to explain the adjustments provided in your "Pro Forma Adjustments" column. Please tell us where you include "Note 4" in your Pro Forma Financial Statements for the Spin-Co adjustment. Revise as necessary.

Unaudited Pro Forma Financial Statements for Merger

2) Pro Forma Adjustments, page F-20

23. As it pertains to your Pro Forma Financial Statements reflecting the merger transaction, please :
- Tell us where adjustments "a" through "f" are located. Revise this note to clearly and separately identify the pro forma adjustments that relate to the reverse recapitalization, equity issuance and spin. Where multiple adjustments are presented as a summed pro forma adjustment, revise to quantify and explain each adjustment included in the total. For example, we note the additional paid in capital adjustment is comprised of (a)(b)(c)(d)(e) and (f).; and
 - Explain how "Total pro forma shares outstanding" of 34,780 disclosed in adjustment "m" agrees to the "weighted average common shares outstanding" presented in your "Pro Forma Consolidated" column.

General

24. We note your disclosure under Item 2.01 and Item 3.02 regarding the issuance of Innovate securities in connection with the merger. Please provide the disclosure required by Item 10 of Form 10 as to all securities of the registrant sold by the registrant within the past three years which were not registered under the Securities Act. Refer to Item 701 of Regulation S-K.
25. Please provide the disclosure required by Item 11 of Form 10. Refer to Item 202 of Regulation S-K.

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 Sarmiento at (202) 551-3798 with any other questions.

Division of Corporation Finance
Office of Healthcare & Insurance

cc: Dan Horwood