



DIVISION OF
CORPORATION FINANCE

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

February 28, 2018

Corey Fishman
President and Chief Executive Officer
Iterum Therapeutics Ltd.
Block 2 Floor 3, Harcourt Centre
Harcourt Street
Dublin 2, Ireland

Re: Iterum Therapeutics Ltd.
Draft Registration Statement on Form S-1
Submitted February 2, 2018
CIK No. 0001659323

Dear Mr. Fishman:

We have reviewed your draft registration statement 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 this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

Prospectus Summary

Overview, page 1

1. Please clarify the meaning of any scientific or technical terms the first time they are used in order to ensure that lay readers will understand the disclosure. For example, please briefly explain what you mean by "gram-negative thiopenem" and "carbapenems." Please also expand your discussion of minimum inhibitory concentration on page 92 to clarify what you mean that "90% of the isolates are inhibited."

Our Solution: Sulopenem Program, page 2

2. We note your disclosure that adverse event data from Phase 1 and Phase 2 clinical trials provides reassurance for the overall safety profile of sulopenem, similar to that of marketed carbapenams. We also note your statement on page 83 that such clinical trials provided evidence to support sulopenem's safety and efficacy. Please revise your disclosure here and throughout your prospectus, e.g., on pages 97 and 100, to remove any conclusions regarding the safety or efficacy of your product candidates as these determinations are solely within the authority of the U.S. Food and Drug Administration and comparable regulatory bodies, and which are continually assessed during all phases of clinical trials. We will not object to statements that the product candidate was well tolerated, that trial participants experienced no serious adverse events, etc. With respect to statements that your clinical trials provide evidence to support efficacy, you may present a balanced summary of the data from the clinical trials but not your conclusions that the data support a determination of efficacy. Similarly, revise your discussion of your preclinical trials on page 93 to describe the endpoints in terms of the objective data points.
3. Please balance your summary of the composition of matter patent that you have exclusively licensed from Pfizer Inc. by disclosing that none of the licensed patents cover the intravenous formulation of sulopenem.

Emerging Growth Company Status, page 4

4. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Use of Proceeds, page 66

5. It appears from your disclosure that the proceeds from the offering will not be sufficient to complete all of your specified uses. Please disclose how far in the development you expect to achieve with the proceeds of this offering and identify the sources of other funds needed to complete development of oral sulopenem and sulopenem through commercialization and establishment of your manufacturing facility. Refer to Instruction 3 to Item 504 of Regulation S-K.

Critical Accounting Policies and Significant Judgments and Estimates

Share-Based Compensation , page 77

6. Please disclose your equity issuances and related common stock valuations during the period presented. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate

our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

Limited Treatment Options, page 87

7. Please describe the significant safety and tolerability concerns. Similarly, describe the risk of serious side effects caused by fluroquinolones on page 88.

Potential Advantages of Oral Sulopenem and Salopenem, page 89

8. Please revise the discussion of the "Promising safety and tolerability profile" on page 90 to include the adverse event data collected as part of the Japanese Phase 2 development program, including an identification of all serious adverse events.

Oral Salopenem and Salopenem Clinical Development Program, page 91

9. The table at the top of page 93 is difficult to understand. Please explain the following:
- The meaning of "N," if N is the number of bacterial samples please clarify whether each of the product or product candidates were tested using the same sample size.
 - Explain the meaning of percentage susceptible, is this a measure of how reactive the tested organism was to the antibiotics?
 - Explain why certain data is highlighted in the table, such as the %S for Ciproflaxin in E.coli.

Additionally, please clarify that ertapenem and meropenem are products that are currently commercially available and the results of your preclinical data demonstrate that these products achieved similar results at lower doses than sulopenem.

10. The table on the bottom of page 93 identifies phase I clinical trials performed using 17 different protocols. However, it appears that the discussion following the table discusses the results from five of these trials. Please explain why you have not provided data from the other trials.
11. For each clinical trial performed, disclose all serious side effects experienced by participants who received your product candidates, including clinical trials performed by Pfizer.

Mean Pharmacokinetic Characteristics of Sulopenem in Humans, page 96

12. Please include a legend to each of the charts on pages 95 and 96 that includes explanatory disclosure necessary for a reader to understand the terms used therein. Your revised discussion should explain the column headings for each table and what the data presented indicates.

Phase 2 Clinical Trials conducted by Pfizer in Japan, 1991-1993, page 97

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Page 4

13. Please explain the meaning of "ITT" and revise your tables on page 98 and 99 to replace the terms "success" and "failure" with the measurable endpoints used to determine whether the results were or were not successful. Additionally, explain how to interpret the numbers presented in the tables.

Planned Phase 3 Clinical Trial, page 99

14. We note your disclosure that the comparative agents are presented in the table on page 100. Please revise your table to ensure that all information presented in the table is legible. Additionally, explain how you will determine whether treatment has resulted in a cure. For example, is cure defined as the absence of symptoms, the absence of certain bacteria or a reduction in certain bacteria. If a reduction in bacteria constitutes a cure, please quantify the reduction that would be considered a cure for purposes of the trial.

Pfizer License Agreement, page 101

15. Please expand your discussion to quantify the value of the Series A preferred shares issued to Pfizer at the time of the issuance.

General

16. Please provide us proofs of all graphics, visual or photographic information you will provide in the printed prospectus prior to its use, for example, in a preliminary prospectus. Please note that we may have comments regarding this material.

You may contact Ibolya Ignat at (202) 551-3636 or Angela Connell at (202) 551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Christine Westbrook at (202) 551-5019 or Suzanne Hayes at (202) 551-3675 with any other questions.

Division of Corporation Finance
Office of Healthcare & Insurance

cc: Charles S. Kim, Esq.