



March 27, 2018

U.S. Securities and Exchange Commission
Office of Healthcare and Insurance
Division of Corporation Finance
100 F Street, N.E.
Washington, D.C. 20549

Attn: Christine Westbrook
Suzanne Hayes

Re: Iterum Therapeutics plc
Amendment No. 1 to the Draft Registration Statement on Form S-1 Submitted March 9, 2018
CIK No. 0001659323

Dear Ms. Westbrook and Ms. Hayes:

On behalf of Iterum Therapeutics plc (“*Iterum*” or the “*Company*”), we submit this letter in response to comments received from the staff (the “*Staff*”) of the Securities and Exchange Commission (the “*Commission*”) by letter dated March 21, 2018 (the “*Comment Letter*”) with respect to the Company’s above referenced Draft Registration Statement on Form S-1 (the “*DRS*”). Concurrently with the submission of this response letter, the Company is submitting an Amendment No. 2 to the Draft Registration Statement (“*DRS Amendment No. 2*”). In addition to addressing the comments raised by the Staff in its letter, the Company has revised DRS Amendment No. 2 to update other disclosures.

For the convenience of the Staff, the numbering of the paragraphs below corresponds to the numbering of the comment in the Comment Letter, the text of which we have incorporated into this response letter for convenience in italicized type and which is followed by the Company’s response. In the responses below, page number references are to the DRS Amendment No. 2.

Amendment No. 1 to Draft Registration Statement on Form S-1 Submitted on March 9, 2018 Prospectus Summary

Overview, page 1

1. *We note your response to comment 1, which we reissue in part. Please explain the meaning of “gram-negative” spectrum thiopenem and its significance in this context.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised the disclosure on page 1 in the DRS Amendment No. 2.

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Our Solution: Sulopenem Program, page 2

2. *We note your response to comment 2, which we reissue in part. We continue to believe your statement that adverse event data from clinical trials conducted by Pfizer “documented a safety profile of sulopenem similar to that of marketed carbapenems” and your reference to “potency against resistant pathogens” present conclusions about safety and efficacy that are inappropriate for you to make. Please revise your disclosure here and similar statements elsewhere in your prospectus, e.g., on pages 85, 92 and 102, to remove such statements. We will not object if you discuss a comparisons of adverse event data and treatment results which include a description of primary endpoints and the statistical significance of these results.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised the disclosures on pages 2, 85, 92 and 102 in the DRS Amendment No. 2.

The Company respectfully advises the Staff that the statement regarding ‘*potency against resistant pathogens*’ refers to the *in vitro*, not the clinical, activity of sulopenem in terms of the low minimum inhibitory concentrations observed, and does not make any clinical conclusions regarding efficacy.

From Neubig RR, *et al.* Pharmacological Reviews 2003; 55 (4): 597–606.: ‘*In the field of pharmacology, potency is a measure of drug activity expressed in terms of the amount required to produce an effect of given intensity. A highly potent drug (e.g., fentanyl, alprazolam, risperidone) evokes a given response at low concentrations, while a drug of lower potency (codeine, diazepam, ziprasidone) evokes the same response only at higher concentrations.*’ As noted in the table on page 95, in the section on ‘Microbiology Surveillance Data,’ sulopenem achieves bacterial killing *in vitro* at drug concentrations well below those concentrations required by the oral antibiotics used to treat uncomplicated urinary tract infections. For example, for *E. coli*, the concentration of sulopenem required is 0.06 µg/mL while for nitrofurantoin it is 16 µg/mL, a 267 fold improvement in potency. As a consequence, these data establish potency. The *in vitro* potency of sulopenem relative to other antibiotics has also been published in the peer reviewed literature [Minamimura M, *et al.* AAC 1993; 37: 1547-1551].

Business

Oral Sulopenem and Sulopenem Clinical Development Program, page 95

3. *We note your response to comment 9. Please expand your disclosure to briefly explain “susceptibility breakpoint” and its relation to minimum inhibitory concentration.*

Response: In response to the Staff’s comment, the Company has revised the disclosure on page 95 in the DRS Amendment No. 2.



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Page Three

Phase 2 clinical trials conducted by Pfizer in Japan, 1991-1993, page 100

4. *We note your response to comment 13, including your point that “success” or “failure” was the investigator’s assessment. We continue to object to the characterization as it is an indication of efficacy which is within the FDA’s sole authority to determine after the conclusion of all clinical trials. We will not object to disclosure relating to trials indicating the number of instances in which primary end points were met or were not met. Please replace the “success” and “failure” captions with the measurements used to make these determinations.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised the disclosure on page 100 in the DRS Amendment No. 2. The Phase 2 clinical trials conducted in Japan with IV sulopenem were designed to collect investigator assessments of efficacy and safety based on resolution of symptoms, pyuria and bacteriuria, as specified in the protocols under ‘*Criteria For Evaluation Of Clinical Efficacy Of Antimicrobial Agents On Urinary Tract Infection*’. The tables pertaining to the Phase 2 trials in Japan shown on page 100 are titled so as to indicate that the results presented are based on the investigators assessment of efficacy. The success and failure determinations are, in fact, the ‘*number of instances in which primary end points were met or were not met.*’

Please contact me at (858) 550-6420 with any questions or further comments regarding our responses to the Staff’s Comments.

Sincerely,

/s/ Charles S. Kim

Charles S. Kim

cc: Corey Fishman, *Iterum Therapeutics plc*
Michael Dunne, *Iterum Therapeutics plc*
Judith Matthews, *Iterum Therapeutics plc*
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