May 21, 2020

## **By Electronic Submission**

Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549

Attention: Jeffrey Gabor

Re: Iterum Therapeutics plc Amendment No. 2 to Registration Statement on Form S-1 Filed April 30, 2020 File No. 333-237326

## Ladies and Gentlemen:

On behalf of Iterum Therapeutics plc (the "Company"), this letter is submitted in response to comments contained in a letter, dated May 14, 2020 (the "Letter"), from the Staff (the 'Staff') of the Office of Life Sciences of the Division of Corporation Finance of the Securities and Exchange Commission (the "Commission") to Corey Fishman, the Company's Chief Executive Officer, relating to the above referenced Amendment No. 2 ("Amendment No. 2") to the Registration Statement on Form S-1 (the "Registration Statement"). Reference is also made to the letter, dated April 23, 2020 (the "April 23 Letter"), from the Staff relating to the Registration Statement and the Company's response letter thereto, dated April 30, 2020 (the "April 30 Response"). The responses contained herein are based on information provided to us by representatives of the Company. The responses are keyed to the numbering of the comments in the Letter and to the headings used in the Letter. Capitalized terms used herein but not defined have the meanings ascribed to them in Amendment No. 2 to the Registration Statement.

## Amendment No. 2 to Registration Statement on Form S-1 filed April 30, 2020

## General

1. We note your revisions in response to prior comment 5. Please provide us with a detailed legal analysis as to whether the royalty-linked notes are asset-backed securities. In providing your analysis, please consider Item 1101(c) of Regulation AB, Section 3(a)(79) of the Exchange Act, and Regulation AB Compliance and Disclosure Interpretation 301.03.

Response: The Royalty-Linked Notes are not asset-backed securities as defined in Item 1101(c) of Regulation AB or Section 3(a)(79) of the Securities Exchange Act of

Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109

Beijing Berlin Boston Brussels Denver Frankfurt London Los Angeles New York Palo Alto San Francisco Washington

1934, as amended (the "Exchange Act"), and the intra-group loan made and expected to be made by Iterum Therapeutics Bermuda Limited (<u>fterum Bermuda</u>") to the Company with the net proceeds from the Private Placement and, if any, from the offering of the Royalty-Linked Notes in the Rights Offering does not render the Royalty-Linked Notes asset-backed securities within the meaning of either definition.

The defining characteristic of an "asset-backed security" under Item 1101(c) of Regulation AB is that a security be "primarily serviced by the cash flows of a discrete pool of receivables or other financial assets, either fixed or revolving, that by their terms convert into cash within a finite time period". Similarly, the definition of "asset-backed security" under Section 3(a)(79) of the Exchange Act specifically requires that a security be "collateralized" by a "self-liquidating financial asset" allowing the security holder "to receive payments that depend primarily on cash flow from the asset". In other words, asset-backed securities are securities that are supported by a pool of assets that by their terms convert to cash, or where payment by the issuer depends on the payment to or through the issuer of specific obligations of third parties.

In contrast, the Royalty-Linked Notes are not serviced by a discrete pool of receivables or other financial assets, either fixed or revolving, and there are no specific payment obligations of third parties to or contracts with the Company on which payment of the Royalty-Linked Notes depends. The payment obligations with respect to the Royalty-Linked Notes depend upon the Company developing, commercializing and marketing its product candidates and drug products, which is the Company's core business. Any amounts payable with respect to the Royalty-Linked Notes will not be based primarily, or at all, on the performance of financial assets in a pool. Rather, as drug products are sold to customers, the amount of the Company's recognized Net Revenues will be used as a measurement tool, or reference mechanism, to determine the amount payable on the Royalty-Linked Notes pursuant to the indenture governing the notes. The money to fund any payments due on the Royalty-Linked Notes will come from the Company's cash on hand, from which the Company's other business obligations will also be paid.

Moreover, when and if the Company receives revenues from product sales, it is not required to set anything aside in a lockbox or otherwise, and there is no requirement in the indenture governing the Royalty-Linked Notes to use the funds received as sales proceeds to satisfy the payment obligations under the Royalty-Linked Notes. Likewise, there is no pledge of any revenue streams or other assets under the indenture. As such, there are no "rights or other assets designed to assure the servicing or timely distributions of proceeds" to holders of the Royalty-Linked Notes. Cash used to satisfy payment obligations under the Royalty-Linked Notes can come from any source and payments are due based on revenues earned, as opposed to revenues actually received, by the Company.

<sup>1</sup> Item 1101(c)(1) of Regulation AB.

These terms are underlined by the fact that customers for the products do not exist yet, and accordingly there are no outstanding contracts or other obligations to purchase any products and no pending receivables owing in respect of any products. As such, there are no receivables or other assets earmarked, segregated or "collateralized" for satisfaction of payments on the Royalty-Linked Notes.

Because there is no pool of receivables or financial assets collateralizing the Royalty-Linked Notes, there are no assets funding the obligations under the Royalty-Linked Notes that "convert into cash within a finite time period" or that are "self-liquidating". As referenced above, the cash flows from the Company's sales of products that could generate income to satisfy payment obligations under the Royalty-Linked Notes are contingent on the success of the Company's future business activities, which is inconsistent with the meaning of "self-liquidating".

For these reasons, the Royalty-Linked Notes are fundamentally distinct from asset-backed securities, and do not fall within the definition of asset-backed securities. Asset-backed securities are securities backed by specific financial assets, receivables or other self-liquidating collateralized assets that allow the holder to receive payments depending "primarily on the cash flows generated by the assets in the underlying pool".5 The Royalty-Linked Notes satisfy none of those characteristics.

There is an additional aspect of the structure of the Royalty-Linked Notes that should be addressed in connection with consideration of whether the Royalty-Linked Notes are asset-backed securities. As disclosed in the Registration Statement, Iterum Bermuda is a direct wholly-owned finance subsidiary of the Company with no independent operations other than financing activities. Iterum Bermuda has no assets other than the right to be paid by the Company under the intra-group loans made and expected to be made by Iterum Bermuda to the Company with the net proceeds from the Private Placement and, if any, from the Rights Offering, and has no liabilities other than the administration of the Royalty-Linked Notes and Exchangeable Notes pursuant to the applicable indentures. The intra-group loan provides that as the Company generates net revenue from sales of products, causing a payment obligation to become owing under the Royalty-Linked Notes, a corresponding payment obligation of the Company to Iterum Bermuda is also created under the intra-group loan.

This "back to back" loan is meant to mirror payment obligations of Iterum Bermuda to the holders of the Royalty-Linked Notes with payment obligations of the Company to Iterum Bermuda, such that Iterum Bermuda will have a right to payment from the

- 3 Item 1101(c)(1) of Regulation AB.
- Section 3(a)(79)(A) of the Exchange Act.
- 5 Asset-Backed Securities, Adopting Release No. 33-8518 (December 22, 2004).

<sup>2</sup> Section 3(a)(79)(A) of the Exchange Act.

Company at the same time that Iterum Bermuda is required to make payments to the holders of the Royalty-Linked Notes. As such, the intra-group loan structure creates a mechanism for funds to flow from the Company to Iterum Bermuda and ultimately to the holders of Royalty-Linked Notes. In addition, as disclosed in the Registration Statement, the Royalty-Linked Notes are supported by the guarantees from the Guarantors (each of the Company and the Company's other subsidiaries), apart from the intra-group loan. These guarantees, which are not collateralized or otherwise backed by any specific assets, create direct obligations of the Guarantors, including the Company, in support of the Royalty-Linked Notes, such that the recourse for the Royalty-Linked Notes is not limited to the intra-company loan payments and is therefore not "asset-backed" within the meaning of the relevant definitions.

Because the intra-group loan is, in a sense, a specific financial asset of Iterum Bermuda that is indirectly related to the payment obligations of Iterum Bermuda in respect of the Royalty-Linked Notes, the question arises whether the intra-group loan would cause the Royalty-Linked Notes to be asset-backed securities, even if, for the reasons outlined above, the Royalty-Linked Notes are not otherwise asset-backed securities. The answer to that question is no. Commission guidance in analogous circumstances sets forth the premise that in determining whether a security is an asset-backed security, "an assessment of the cash flows servicing the payments on the notes requires looking through the [intracompany agreement] to the general account of the [parent company]" to ascertain the underlying reality.6

Here, when we "look through" the intra-group loan, it is clear that the intra-group loan does not change the underlying reality that the Royalty-Linked Notes depend for payment on the ordinary course business operation of the Company and its subsidiaries to develop, commercialize and market product candidates and drug products. Notwithstanding the intra-group loan, investors in the Royalty-Linked Notes will be primarily dependent on the future performance, results of operations and financial condition of the Company and its consolidated subsidiaries for satisfaction of the obligations of Iterum Bermuda and the Guarantors under the Royalty-Linked Notes.

As with the ultimate payments from Iterum Bermuda to the holders of Royalty-Linked Notes, payments under the intra-group loan agreement depend on the "general account" of the Company and are not "based primarily on the performance of the financial assets in the pool's since there are no receivables or assets set aside in a pool or otherwise to support the Company's payment obligations under the intra-group loan. As such, payments from Iterum Bermuda on the Royalty-Linked Notes are dependent on the ability of the Company to generate revenue and make payments under the loan

<sup>6</sup> Compliance and Disclosure Interpretations ("Regulation AB and Related Rules"), Question 301.03 (September 6, 2016).

<sup>7</sup> See id.

<sup>8</sup> Asset-Backed Securities, Adopting Release No. 33-8518 (December 22, 2004).

agreement. Additionally, as described above, the structure of the intra-group loan is "meant to replicate payments" due under the Royalty-Linked Notes and the loan agreement is a "direct liability" of the Company. Therefore, the intra-group loan between the Company and Iterum Bermuda, a finance subsidiary that is 100% owned and controlled by the Company, is not "a separate financial asset servicing payments" on the Royalty-Linked Notes, and the intra-group loan does not render the Royalty-Linked Notes asset-backed securities within the meaning of Item 1101(c) of Regulation AB or Section 3(a)(79) of the Exchange Act. 10

In conclusion, based on the characteristics of the Royalty-Linked Notes and the intra-group loan structure, the definitions of asset-backed securities in Regulation AB and the Exchange Act as well as Commission guidance, including Regulation AB Compliance and Disclosure Interpretation 301.03, the Company does not believe the Royalty-Linked Notes are asset-backed securities.

2. We note your response to prior comment 6. We note that the royalty-linked securities have been titled a "Royalty-Linked Notes" and the concomitant indenture and trustee. Please explain to us how you intend to comply with the Trust Indenture Act of 1939.

**Response:** The Company has filed with the Commission the documentation required to qualify the offering of Royalty-Linked Notes under the Trust Indenture Act of 1939, as amended (the "<u>TIA</u>"), and such documentation and the structure of the Royalty-Linked Notes enable the Company and the indenture trustee, Computershare Trust Company, N.A., to comply with the TIA.

The Royalty-Linked Notes will be issued pursuant to a trust indenture, which is filed as Exhibit 4.4 to the Registration Statement. That trust indenture complies with the requirements of the TIA, as further discussed below. In addition, a statement of eligibility on Form T-1 provided by the indenture trustee to the Company was filed on March 20, 2020 as Exhibit 25.2 to the Registration Statement setting forth the qualifications of the indenture trustee under the TIA. The indenture, the disclosure in the Registration Statement related to the Royalty-Linked Notes and the Form T-1 together include the information required by the TIA, including information (a) to enable the Commission to determine whether the appointed indenture trustee is eligible to act as such under the TIA, (b) regarding the default and notice of default provisions of the trust indenture, and (c) identifying the provisions of the trust indenture addressing the authentication and delivery of the Royalty-Linked Notes and the application of the proceeds thereof, the satisfaction and discharge of the indenture, and the evidence

<sup>9</sup> Compliance and Disclosure Interpretations ("Regulation AB and Related Rules"), Question 301.03 (September 6, 2016).

<sup>10</sup> See id.

required to be furnished by Iterum Bermuda to the indenture trustee as to compliance with the conditions and covenants in the trust indenture. 11

The trust indenture contains the required cross-reference table, setting forth the sections of the trust indenture that correspond to the related sections of the TIA, and the trust indenture contains all applicable provisions required by the TIA. On this basis, the Company believes that the structure and documentation of the Royalty-Linked Notes are in compliance with the TIA, and that the Company and the indenture trustee will be able, through the operation of such documentation and its terms, to comply with the TIA.

The Company's compliance with the TIA in respect of the Royalty-Linked Notes will be consistent with its compliance with the TIA in respect of the Exchangeable Notes issued contemporaneously with the Royalty-Linked Notes. Indeed, the trust indentures for the Royalty-Linked Notes and the Exchangeable Notes are in the same basic forms as one another, and the statements regarding the trust indenture for the Royalty-Linked Notes in the immediately preceding paragraph also apply to the Exchangeable Notes, except that there is a different indenture trustee for the Exchangeable Notes.

The differences between the trust indentures for the Royalty-Linked Notes and the Exchangeable Notes are related to the different economic terms of the respective instruments. The Royalty-Linked Notes and the Exchangeable Notes both represent obligations for the payment of money by Iterum Bermuda, subject to their terms, and as such they are both properly considered debt obligations of Iterum Bermuda. As described in the April 30 Response to prior comment 6 in the April 23 Letter, both the Royalty-Linked Notes and the Exchangeable Notes have general characteristics of debt instruments, including principal and fixed maturity. The amount of principal owing in respect of each debt security is different, as is the manner in which the amount of accrued interest owing in respect of the debt security is calculated. The Exchangeable Notes have a relatively higher amount of principal and permit that principal to be exchanged into equity of the Company upon certain conditions. The Exchangeable Notes also have a fixed rate of regular interest and a relatively smaller variation between the rate of regular interest and the rate of interest in the case of default. By comparison, the Royalty-Linked Notes have a relatively lower amount of principal and no provision that permits the principal to be exchanged for equity. The Royalty-Linked Notes have a variable rate of regular interest that fluctuates on the basis of the RLN Net Revenues earned by the Company on U.S. sales of the Products in the applicable RLN Payment Measurement Period, rather than on the basis of the time over which the principal amount in respect of the Royalty-Linked Notes remains outstanding, and the Royalty-Linked Notes have a relatively larger possible variation between the rate of regular interest and the prime-rate-based rate of default interest. The maturity date for the Exchangeable Notes is in 2025, and the corresponding date for the Royalty-Linked Notes is in 2045. The indentures also

<sup>11</sup> Section 305(a)(1) and (2) of the TIA.

address the tax treatment of the notes. The indenture for the Exchangeable Notes provides that the Exchangeable Notes will be treated as debt and issued with original issue discount ("OID") for U.S. federal income tax purposes, while the Royalty-Linked Notes should not have OID because the indenture for the Royalty-Linked Notes provides that the Royalty-Linked Notes will be treated as contractual rights to receive payments and not as debt for U.S. federal income tax purposes.

The differences in the economic terms of the Exchangeable Notes and the Royalty-Linked Notes do not, however, distinguish the ability of Iterum Bermuda or the respective indenture trustees from complying with the TIA in respect of the related securities. Many debt instruments are issued under TIA-qualified indentures with a broad variety of economic terms, including principal amount, type and rate of interest, maturity date, and OID or lack thereof, while it is the structure and documentation of the issuances that comply with, and allow the issuers and indenture trustees to comply with, the TIA.

In conclusion, the Company believes the structure and documentation of the Exchangeable Notes and the Royalty-Linked Notes demonstrate that Iterum Bermuda and the respective indenture trustees can comply with the TIA in respect of issuances of both the Exchangeable Notes and the Royalty-Linked Notes.

If you have any further questions or comments, or if you require any additional information, please contact the undersigned by telephone at (212) 937-7206 or e-mail at brian.johnson@wilmerhale.com. Thank you for your assistance.

Very truly yours,

/s/ Brian A. Johnson

Brian A. Johnson

cc: Corey Fishman, Iterum Therapeutics plc