#### VIA EDGAR

May 25, 2023



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

Attn: Frank Wyman

Angela Connell

Division of Corporation Finance

Office of Life Sciences

RE: Iterum Therapeutics plc

Form 10-K for Fiscal Year Ended December 31, 2022

Filed March 16, 2023 File No. 001-38503

Dear Mr. Wyman and Ms Connell,

Iterum Therapeutics plc (the "Company", "we", "our") sets forth below its responses to the comments of the staff (the "Staff") of the United States Securities and Exchange Commission as sent by you on May 11, 2023, relating to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 ("2022 Form 10-K"), as filed on March 16, 2023. To facilitate your review, we have included in bold italics below the Staff's comments.

#### Form 10-K for Fiscal Year Ended December 31, 2022

Notes to Consolidated Financial Statements Note 2: Summary of Significant Accounting Policies Royalty-Linked Notes, page 123

1. We note your disclosure that your royalty-linked notes (RLNs), upon recognition, were carried as debt instruments at amortized cost, but at the time they became exchange listed, qualified for derivative accounting treatment. Please provide us your accounting analysis supporting both your initial accounting treatment for your RLNs and subsequent accounting treatment at the time they became exchange listed. As part of your analysis, explain your consideration of whether your RLNs contained any features requiring bifurcation prior to the listing on an exchange.

On January 21, 2020, we completed a private placement ("Private Placement") pursuant to which our wholly owned subsidiary, Iterum Therapeutics Bermuda Limited ("Iterum Bermuda"), issued and sold approximately \$51.6 million aggregate principal amount of 6.500% Exchangeable Senior Subordinated Notes due 2025 ("Exchangeable Notes") and \$0.1 million aggregate principal amount of Limited Recourse Royalty-Linked Subordinated Notes ("RLNs" and, together with the Exchangeable Notes, the "Securities" and each a "Security") to a group of accredited investors. On September 8, 2020, we completed a rights offering ("the Rights Offering") pursuant to which Iterum Bermuda issued and sold approximately \$0.2 million aggregate principal amount of Exchangeable Notes and \$0.44 thousand aggregate principal amount of RLNs to existing shareholders. The

# **Iterum Therapeutics plc**

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Directors: David G. Kelly, Mark Chin (USA), Corey N. Fishman (USA), Brenton K. Ahrens (USA), Beth P. Hecht (USA), Ronald M. Hunt (USA), Michael Dunne (USA)

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Securities were sold in units ("the Units"), with each Unit consisting of an Exchangeable Note in the original principal amount of \$1,000 and 50 RLNs. The Units were sold at a price of \$1,000 per Unit. While the Securities were packaged as a Unit at the closing of the Private Placement and the Rights Offering, each Security was issued under a separate indenture and transferable separately pursuant to the terms of each such indenture. The RLNs entitle holders to payments based on a percentage of our net revenues from potential U.S. sales of specified sulopenem products subject to the terms and conditions of the indenture governing the RLNs. Pursuant to the indenture governing the RLNs, the payments on the RLNs will be up to either 15% or 20% of net revenues from U.S. sales of such products, depending on the indication approved by the FDA. The aggregate payment on each RLN is capped at \$160.00 (or 4,000 times the principal amount of \$0.04 for each such RLN).

In determining the appropriate accounting treatment of the RLNs, in the first instance, we evaluated the accounting treatment of the Units. Our analysis focused on determining whether the Unit represented a single free-standing financial instrument, or whether parts of the Unit could be identified as free-standing financial instruments.

Financial Accounting Standard Board's ("FASB") Accounting Standards Codification's ("ASC") Master Glossary defines a free-standing financial instrument as:

"A financial instrument that meets either of the following conditions:

(a)It is entered into separately and apart from any of the entity's other financial instruments or equity transactions. (b)It is entered into in conjunction with some other transaction and is legally detachable and separately exercisable."

We determined that the RLNs and the Exchangeable Notes were each a "free-standing financial instrument" as they immediately separated on closing of the Private Placement and Rights Offering, were issued pursuant to separate indentures and were transferable separately in accordance with the terms of each such indenture.

Next, we considered whether the RLNs were a debt or a derivative instrument.

First, we reviewed the guidance included in the ASC 815, *Derivatives and Hedging* ("ASC 815") and determined that the RLNs were a derivative instrument based on ASC 815-10-15-83, being a financial instrument with all of the following characteristics:

(a) ASC 815-10-15-83(a)(1) – One or more underlyings: This condition is met as the probability of the approval of the product by the US Food & Drug Administration as well as the net sales of the products represent multiple underlyings.

(b) ASC 815-10-15-83(a)(2) — One or more notional amounts or payment provisions or both: This condition is met as the RLNs contain a payment provision that specifies a fixed percentage to be paid if net sales (underlying) occurs.

(c) ASC 815-10-15-83(b) — Initial net investment: This condition is met as the initial net investment was lower than what would otherwise be paid to get the same exposure to the underlying. The proceeds of the Units allocated to the RLNs was lower than the fair value of the RLNs at the time of issuance.

(d)ASC 815-10-15-83(c) – Net settlement: This condition is met as the payments pursuant to the RLNs are made in cash and thus meet the net settlement criteria of ASC 815-10-15-99(a). ASC 815-10-15-99(a) states that "neither party is required to deliver an asset that is associated with the underlying and that has a principal amount, stated amount, face value, number of shares, or other denomination that is equal to the notional amount (or the notional amount plus a premium or minus a discount)." As the cash payment is not considered associated with the underlying, we determined that the net settlement criterion was met.

Having determined that the RLNs were a derivative instrument pursuant to ASC 815, we then considered whether any of the exceptions to derivative accounting outlined in ASC 815-10-15-13 through 15-82 applied, noting

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that ASC 815-10-15-10 states that "the guidance in the General Subsections of this Subtopic applies to all derivative instruments, as that term is defined in paragraph 815-10-15-83, unless explicitly excluded by this Subsection (see paragraphs 815-10-15-13 through 15-82)". We considered, in particular, the exception described in ASC 815-10-15-59 through 15-62 (i.e., certain contracts that are not traded on an exchange). Pursuant to ASC 815-10-15-59 (d), contracts that are not exchange-traded are not subject to the requirements of ASC 815 "if the underlying on which the settlement is based is specified volumes of sales or service revenues of the contract". As the RLNs were not initially exchange traded and entitle holders to payments based on a percentage of our net revenues from U.S. sales of certain products, we concluded that the RLNs were excluded from ASC 815 and therefore would not be required to be accounted for as derivatives. In addition, because we determined that the RLNs, as an instrument, met the definition of a derivative in its entirety, we determined the guidance in ASC 815 related to embedded derivatives was not applicable.

Accordingly, and in conjunction with ASC 470-10-25-2, we determined that debt classification was appropriate. We looked to ASC 470-10-35-3 and the RLNs were measured at amortized cost with amortization recognized as an interest expense over the term of the debt instrument using the effective interest method described in ASC 835-30. At each reporting period we assessed the valuation of the RLNs for any significant changes to the facts and circumstances in the initial valuation which would impact the carrying value, and if required, made adjustments to the amortization of the liability.

In January 2021, the RLNs were listed on the Bermuda Stock Exchange pursuant to Section IIIB of the Bermuda Stock Exchange Listing Regulations and as such the scope exception for contracts which were not exchange-traded in ASC 815-10-15-59 (d) that we relied upon in the initial accounting ceased to apply. As a result, we began accounting for the RLNs from January 2021 as a free-standing derivative under ASC 815 and the RLNs are remeasured at fair value at each reporting date.

# Note 3: Fair Value of Financial Assets and Liabilities, page 126

2. We note your disclosure on page 128 that the fair value of your RLNs was estimated using a discounted cash flow analysis with key inputs being the terms of the indenture governing the RLNs, the expected cash flows to be received by holders of the RLNs based on management's revenue forecasts of U.S. sulopenem sales and a risk-adjusted discount rate to derive the net present value of expected cash flows. Please tell us how you determined that the use of a discounted cash flow model to estimate the fair value of your RLNs meets the objective of fair value measurement set forth in ASC 820 considering your disclosure that the RLNs have been listed on the Bermuda Stock Exchange since January 2021. In this regard, specifically explain how you considered ASC 820-10-35-6 and ASC 820-10-35-16AA in determining whether transactions on the Bermuda Stock Exchange provided relevant observable inputs for you to value your RLNs.

In January 2021, the RLNs were listed on the Bermuda Stock Exchange pursuant to Section IIIB of the Bermuda Stock Exchange Listing Regulations. The principal purpose of the listing was to avail of the quoted Eurobond exemption from Irish interest withholding tax. So long as, at the time interest is paid on the RLNs, the RLNs are listed on a recognized stock exchange, such as the Bermuda Stock Exchange, and are held in a recognized clearing system, such as DTC (or, if not so held, payments on the RLNs are made through a paying agent not in Ireland), interest on the RLNs can be paid by us and any paying agent acting on our behalf without any withholding or deduction for or on account of Irish income tax.

As noted above, following the listing of the RLNs on the Bermuda Stock Exchange in January 2021, the exemption for contracts which are not exchange-traded in ASC 815-10-15-59 (d) ceased to apply and the RLNs were treated as a free-standing derivative under ASC 815. Since that time, the Company recognizes the RLNs at fair value using a discounted cash flow analysis with key inputs being the terms of the indenture governing the RLNs, the expected cash flows to be received by holders of the RLNs based on our revenue forecasts of U.S. sulopenem sales and a risk-adjusted discount rate to derive the net present value of expected cash flows.

When determining the valuation technique to use following listing of the RLNs on the Bermuda Stock Exchange, we considered the provisions of ASC 820-10-35-6 and ASC 820-10-35-16AA, noting in particular that

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"if there is a principal market for the asset and liability, the fair value measurement shall represent the price in that market (whether that price is directly observable or estimated using another valuation technique)" and that a reporting entity shall "maximize the use of relevant observable inputs to meet the objective of a fair value measurement, which is to estimate the price at which an orderly transaction to transfer the liability or instrument classified in shareholders' equity would take place between market participants at the measurement date under current market conditions". However, notwithstanding that the RLNs have been listed on the Bermuda Stock Exchange since January 2021, since that date there has been no active trading market created in the RLNs and as such, there is no observable "price" based on that market. Without any other observable inputs available to estimate the price at which a transfer of the liability would take place between market participants pursuant to ASC 820-10-35-16AA, we determined that a discounted cash flow analysis, being a valuation technique consistent with the income approach pursuant to ASC 820-10-35-24A, was the most appropriate valuation technique to use in the circumstances and for which sufficient data is available to measure fair value. We will continue to monitor the potential trading of this instrument and should the RLNs become actively traded, we will incorporate that information in the determination of fair value under ASC 820.

Please advise us if we can provide any further information or assistance to facilitate your review.

Very truly yours,

/s/ Judith M. Matthews Judith M. Matthews Chief Financial Officer

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