UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 14, 2021

Iterum Therapeutics plc		
(Exact name of registrant as specified in its charter)		
Ireland	**001-38503**	**98-1283148**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Block 2 Floor 3, Harcourt Centre,	
Harcourt Street,	**Not Applicable**
Dublin 2, Ireland	
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **+353 1 903 8920**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Ordinary Shares, par value $0.01 per share	ITRM	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02. Results of Operations and Financial Condition.

On May 14, 2021, Iterum Therapeutics plc, or Iterum Therapeutics, issued a press release announcing its financial results for the first quarter ended March 31, 2021. A copy of the press release is furnished herewith as Exhibit 99.1.

The information in this current report on Form 8-K, including the press release attached as Exhibit 99.1 hereto, is being furnished, but shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Iterum Therapeutics, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Iterum Therapeutics plc, dated May 14, 2021

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Iterum Therapeutics plc

Dated: May 14, 2021

By: /s/ Corey N. Fishman
Corey N. Fishman
Chief Executive Officer

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

Iterum Therapeutics Reports First Quarter 2021 Financial Results

FDA Review of NDA for Oral Sulopenem Continues;
Current Prescription Drug User Fee Act (PDUFA) date of July 25, 2021

Cash Runway into First Half of 2023

Company to host conference call today at 8:30am ET

DUBLIN, Ireland and CHICAGO, May 14, 2021 -- Iterum Therapeutics plc (Nasdaq: ITRM), a clinical-stage pharmaceutical company focused on developing next generation oral and IV antibiotics to treat infections caused by multi-drug resistant pathogens in both community and hospital settings, today reported financial results for the first quarter ended March 31, 2021.

"We continue to prepare for a U.S. Food and Drug Administration (FDA) advisory committee meeting and look forward to clarity from the FDA on timing. In the meantime, the FDA continues its review of our new drug application (NDA) for oral sulopenem for the treatment of uncomplicated urinary tract infections (uUTI) in patients with a quinolone non-susceptible organism and has not advised us of any change to the current PDUFA goal date of July 25, 2021," said Corey Fishman, Chief Executive Officer. "With an FDA decision on oral sulopenem expected in the second half of 2021 and a strong cash position, we are preparing for a launch of oral sulopenem into the community in the fourth quarter of 2021, if approved."

Highlights and Recent Events

- **NDA priority review by the FDA is ongoing with current PDUFA goal date of July 25, 2021:** In January 2021, the FDA accepted for review our NDA for uUTI in patients with a quinolone non-susceptible organism. The FDA has designated our application as a priority review and consequently assigned a PDUFA goal date for completion of the review of oral sulopenem of July 25, 2021. The FDA previously planned to hold an advisory committee meeting for oral sulopenem on June 2, 2021 but this meeting was postponed to allow the FDA more time to review material provided by the Company in support of the NDA. A new date for such meeting, if required by the FDA, has not yet been confirmed.
- **Extended cash runway into first half of 2023:** In February 2021, we received total net proceeds of $74.3 million from an underwritten public offering and a registered direct offering. Based on our current operating plans, we believe our cash, cash equivalents and short-term investments of $100.5 million as of March 31, 2021 allows us to operate into the first half of 2023. As of March 31, 2021, we had approximately 179.1 million ordinary shares outstanding.

- **Ongoing collaboration with a third-party provider of commercialization services:** In February 2021, we engaged EVERSANA™, a leading provider of commercial services to the life science industry, and we have initiated pre-launch activities. We are in the process of finalizing an agreement with EVERSANA™ to provide commercialization services to launch oral sulopenem, if approved.

First Quarter 2021 Financial Results

As of March 31, 2021 , Iterum had cash, cash equivalents and short-term investments of $100.5 million. Based on its current operating plan, I terum expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations into the first half of 2023.

Research and development expenses for the first quarter of 2021 were $2.5 million compared to $9.7 million for the same period in 2020. The decrease for the period was primarily due to the completion of our Phase 3 clinical trials in 2020.

General and administrative (G&A) expenses for the first quarter of 2021 were $3.4 million compared to $3.2 million for the same period in 2020. The increase for the period was primarily due to higher spend on pre-commercialization activities and consultants to support our G&A function, partially offset by lower G&A headcount.

Adjustments to the fair value of derivatives for the first quarter 2021 were $90.1 million compared to $1.7 million for the same period in 2020. This non-cash adjustment in the first quarter of 2021 related to an increase in the value of the derivative components associated with Iterum's 6.500% Exchangeable Senior Subordinated Notes due 2025 (the Exchangeable Notes) and Limited Recourse Royalty-Linked Subordinated Notes (the Royalty-Linked Notes) issued in 2020 primarily as a result of an increase in the price of Iterum's ordinary shares and an increase in Iterum's market capitalization during the period.

For the first quarter of 2021, Iterum reported a net loss of $98.9 million compared to a net loss of $16.1 million for the same period in 2020 due largely to non-cash adjustments to the derivative liabilities associated with Iterum's Exchangeable Notes and Royalty-Linked Notes. Iterum reported non-GAAP net loss[1] of $6.1 million for the first quarter of 2021 compared to non-GAAP net loss of $13.4 million for the same period in 2020.

Upcoming Investor Presentations

- Fireside chat at the RBC Capital Markets Global Healthcare Virtual Conference on Wednesday May 19, 2021 at 4:15pm ET
- Corporate presentation at the Jefferies Virtual Healthcare Conference on Tuesday, June 1, 2021 at 1:00pm ET
- Corporate presentation at the JMP Securities Life Sciences Conference on Thursday, June 17, 2021 at 12:00pm ET

Conference Call and Webcast Details

[1] Reconciliations of applicable GAAP reported to non-GAAP adjusted information are included at the end of this press release.

- Iterum will host a conference call and webcast today, Friday, May 14, 2021 at 8:30 a.m. Eastern Time. To register for this conference call, please use this link: https://www.incommglobalevents.com/registration/client/7304/iterum-therapeutics-1st-quarter-2021-financial-results-conference-call/

About Sulopenem

Sulopenem, a novel penem anti-infective compound with oral and IV formulations, has demonstrated potent *in vitro* activity against a wide variety of gram-negative, gram-positive and anaerobic bacteria resistant to other antibiotics. We believe that sulopenem and oral sulopenem have the potential to be important new treatment alternatives to address the growing concerns related to antibacterial resistance without the known toxicities of some of the most widely used antibiotics, specifically fluoroquinolones. Our NDA for oral sulopenem for the treatment of uUTI in patients with a quinolone non-susceptible pathogen is under FDA review and has a current PDUFA goal date of July 25, 2021.

About Iterum Therapeutics plc

Iterum Therapeutics plc is a clinical-stage pharmaceutical company dedicated to developing differentiated anti-infectives aimed at combatting the global crisis of multi-drug resistant pathogens to significantly improve the lives of people affected by serious and life-threatening diseases around the world. Iterum Therapeutics is advancing its first compound, sulopenem, a novel penem anti-infective compound, in Phase 3 clinical development with oral and IV formulations. Sulopenem has demonstrated potent *in vitro* activity against a wide variety of gram-negative, gram-positive and anaerobic bacteria resistant to other antibiotics. Iterum Therapeutics has received Qualified Infectious Disease Product (QIDP) and Fast Track designations for its oral and IV formulations of sulopenem in seven indications. For more information, please visit http://www.iterumtx.com.

Non-GAAP Financial Measures

To supplement Iterum Therapeutics' financial results presented in accordance with U.S. generally accepted accounting principles, or GAAP, Iterum Therapeutics presents non-GAAP adjusted net loss and non-GAAP net loss per share to exclude from reported GAAP net loss and GAAP net loss per share for the three months ended March 31, 2021 and March 31, 2020, the interest expense associated with accrued interest on the Exchangeable Notes, or ENs, payable in cash, shares or a combination of both upon exchange, redemption or at January 31, 2025, or the Maturity Date, whichever is earlier ($0.436 million); the non-cash amortization of the ENs and Royalty-Linked Notes ($2.312 million); and the non-cash adjustments to the fair value of derivatives ($90.103 million) for the three months ended March 31, 2021, the interest expense associated with accrued interest on the Exchangeable Notes, or ENs, payable in cash, shares or a combination of both upon exchange, redemption or at January 31, 2025, or the Maturity Date, whichever is earlier ($0.652 million); the non-cash amortization of the ENs and Royalty-Linked

Notes ($1.613 million); one-time, non-capitalized financing transaction costs ($2.130 million); and the offsetting non-cash adjustments to the fair value of derivatives ($1.679 million) for the three months ended March 31, 2020.

Iterum Therapeutics believes that the presentation of non-GAAP adjusted net loss and non-GAAP net loss per share, when viewed with its results under GAAP and the accompanying reconciliation, provides useful supplementary information to, and facilitates additional analysis by, investors, analysts, and Iterum Therapeutics' management in assessing Iterum Therapeutics' performance and results from period to period. These non-GAAP financial measures closely align with the way management measures and evaluates Iterum Therapeutics' performance. These non-GAAP financial measures should be considered in addition to, and not a substitute for, or superior to, net loss or other financial measures calculated in accordance with GAAP. Non-GAAP adjusted net loss and non-GAAP net loss per share are not based on any standardized methodology prescribed by GAAP and represents GAAP net loss, which is the most directly comparable GAAP measure, adjusted to exclude the interest expense associated with accrued interest on the ENs payable in cash, shares or a combination of both upon exchange, redemption or at the Maturity Date, whichever is earlier; the non-cash amortization of the ENs and Royalty-Linked Notes; one-time, non-capitalized financing transaction costs and the non-cash adjustments to the fair value of derivatives for the three months ended March 31, 2021 and March 31, 2020. Because of the non-standardized definitions of non-GAAP financial measures, non-GAAP adjusted net loss and non-GAAP net loss per share used by Iterum Therapeutics in the accompanying press release and tables therein has limits in its usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies. A reconciliation of non- GAAP adjusted net loss to GAAP net loss and non-GAAP net loss per share to GAAP net loss per share have been provided in the tables included in the accompanying press release.

Forward Looking Statements

This press release contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding the Company's plans, strategies and prospects for its business, including with respect to the timing of review by the FDA of the Company's NDA for oral sulopenem and the related PDUFA date, the holding of an FDA advisory committee meeting to discuss the NDA, and the Company's expectations for potential approval of the NDA on the PDUFA date, the market potential for sulopenem, commercialization activities including the ability to enter into a definitive agreement with respect to commercialization services and to successfully launch oral sulopenem, if approved, and the sufficiency of the Company's cash resources to execute its strategy. In some cases, forward-looking statements can be identified by words such as "may," "believes," "intends," "seeks," "anticipates," "plans," "estimates," "expects," "should," "assumes," "continues," "could," "would," "will," "future," "potential" or the negative of these or similar terms and phrases. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include all matters that are not historical facts. Actual future results may be materially different from what is expected due to

factors largely outside the Company's control, including the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, changes in public policy or legislation, commercialization plans and timelines, if oral sulopenem is approved, the actions of third-party clinical research organizations, suppliers and manufacturers, the accuracy of the Company's expectations regarding how far into the future the Company's cash on hand will fund the Company's ongoing operations, the impact of COVID-19 and related responsive measures thereto, risks and uncertainties concerning the outcome, impact, effects and results of the Company's evaluation of corporate, strategic, financial and financing alternatives, including the terms, timing, structure, value, benefits and costs of any corporate, strategic, financial or financing alternative and the Company's ability to complete one at all and other factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on May 14, 2021, and other documents filed with the SEC from time to time. Forward-looking statements represent the Company's beliefs and assumptions only as of the date of this press release. Except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

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ITERUM THERAPEUTICS PLC
Condensed Consolidated Statement of Operations
(In thousands except share and per share data)
(Unaudited)

	Three months ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	(2,451)	(9,743)
General and administrative	(3,396)	(3,151)
Total operating expenses	(5,847)	(12,894)
Operating loss	(5,847)	(12,894)
Interest expense, net	(2,952)	(2,596)
Financing transaction costs	-	(2,130)
Adjustments to fair value of derivatives	(90,103)	1,679
Other income / (expense), net	41	(38)
Income tax expense	(60)	(121)
Net loss attributable to ordinary shareholders	$ (98,921)	$ (16,100)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.81)	$ (1.08)
Weighted average ordinary shares outstanding – basic and diluted	121,549,083	14,868,973
Reconciliation of non-GAAP net loss to GAAP net loss		
Net loss - GAAP	$ (98,921)	$ (16,100)
Interest expense - accrued interest and amortization on Exchangeable Notes and Royalty-Linked Notes	2,748	2,267
Financing transaction costs - not capitalized	-	2,130
Adjustments to fair value of derivatives	90,103	(1,679)
Non-GAAP net loss	$ (6,070)	$ (13,382)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.81)	$ (1.08)
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.05)	$ (0.90)

ITERUM THERAPEUTICS PLC
Condensed Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	As of March 31, 2021	**As of December 31, 2020**
Cash, cash equivalents and short-term investments	$ 100,508	$ 14,508
Other assets	14,657	18,284
Total assets	**$ 115,165**	**$ 32,792**
Long-term debt, less current portion	$ 6,094	22,462
Royalty-linked notes, less current portion	28,798	13,389
Derivative liabilities	28,868	28,865
Other liabilities	19,888	18,635
Total liabilities	$ 83,648	$ 83,351
Total shareholders' equity / (deficit)	$ 31,517	$ (50,559)
Total liabilities and shareholders' equity / (deficit)	**$ 115,165**	**$ 32,792**