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): August 13, 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 August 13, 2021, Iterum Therapeutics plc issued a press release announcing its financial results for the first quarter ended June 30, 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 August 13, 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: August 13, 2021

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

Iterum Therapeutics Reports Second Quarter 2021 Financial Results and Provides Business Update

--Type A meeting with FDA expected late Q3 to define pathway to potential approval for Oral Sulopenem following July's Complete Response Letter--

--Cash Runway into Second Half of 2023--

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

DUBLIN, Ireland and CHICAGO, August 13, 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 second quarter ended June 30, 2021.

"Despite our disappointment with the FDA's Complete Response Letter ("CRL"), we've begun preparations for the Type A meeting with the FDA expected later this quarter and we hope to receive adequate guidance and agreement with the FDA on a path forward that will lead to resubmission of our New Drug Application ("NDA") as quickly as possible," said Corey Fishman, Chief Executive Officer.

Highlights and Recent Events

- **FDA completes review of NDA:** On July 23, 2021, we received a CRL from the U.S. Food and Drug Administration ("FDA") with respect to our NDA for oral sulopenem for the treatment of uncomplicated urinary tract infections in patients with a quinolone non-susceptible organism, stating that the FDA could not approve the NDA in its present form. The CRL provided that additional data are necessary to support approval of oral sulopenem and recommended that we conduct at least one additional adequate and well-controlled clinical trial, potentially using a different comparator drug. Additionally, the FDA recommended that we conduct further non-clinical investigation to determine the optimal dosing regimen, although the FDA stated that this recommendation does not raise an approvability issue. We plan to have a Type A meeting with the FDA to identify the next steps as to the potential additional clinical and non-clinical work to support a potential resubmission of the NDA for approval of oral sulopenem. The meeting is expected to take place near the end of the third quarter.

- **Cash runway into second half of 2023:** Based on the current operating plan and subject to final determination of the design and planned conduct of potential additional clinical and non-clinical development for sulopenem, we believe that we are well positioned financially to fund operations into the second half of 2023. Following receipt of the CRL, in order to reduce operating expenses and conserve cash resources, we halted any remaining pre-commercial activities for oral sulopenem and plan to limit spending to essential costs required in connection with the potential resubmission of the NDA. If and when we believe regulatory approval of oral sulopenem appears likely, we plan to resume pre-commercialization activities and negotiations on a definitive agreement for commercialization services. As of June 30, 2021, we had approximately 182.6 million ordinary shares outstanding.

Second Quarter 2021 Financial Results

As of June 30, 2021 , Iterum had cash, cash equivalents and short-term investments of $91.4 million. Based on the current operating plan and subject to final determination of the design and planned conduct of potential additional clinical and non-clinical development for sulopenem, I terum expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations into the second half of 2023.

Research and development expenses for the second quarter of 2021 were $2.7 million compared to $5.0 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 second quarter of 2021 were $4.3 million compared to $3.2 million for the same period in 2020. The increase for the period was primarily due to higher spending 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 second quarter 2021 were $15.8 million compared to $0.0 million for the same period in 2020. This non-cash adjustment in the second quarter of 2021 primarily related to a decrease in the fair value of Iterum's Limited Recourse Royalty-Linked Subordinated Notes (the Royalty-Linked Notes), which were issued in 2020.

For the second quarter of 2021, Iterum reported net income of $7.8 million compared to a net loss of $12.5 million for the same period in 2020 due largely to the non-cash adjustment associated with Iterum's Royalty-Linked Notes in the second quarter of 2021. On a non-GAAP basis, Iterum reported a non-GAAP[1] net loss of $7.2 million for the second quarter of 2021 compared to a non-GAAP net loss of $8.8 million for the same period in 2020.

Upcoming Investor Presentation

- Corporate presentation at the H.C. Wainwright 23rd Annual Global Investment Conference in New York, NY on September 13, 2021 at 12:00pm ET

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

Conference Call Details

- Iterum will host a conference call today, Friday, August 13, 2021 at 8:30 a.m. Eastern Time. The dial-in information for the call is as follows: United States: 1 844 200 6205 (Toll Free); United States (Local): 1 646 904 5544 (Local); All Other Locations: + 44 208 0682 558; Access code: 096194

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 ("GAAP"), Iterum Therapeutics presents non-GAAP adjusted net loss and non-GAAP net loss per share to exclude from reported GAAP net income/(loss) and GAAP net income/(loss) per share, the interest expense associated with accrued interest on the Exchangeable Notes (" ENs"), payable in cash, shares or a combination of both upon exchange, redemption or at January 31, 2025 ("the Maturity Date"), whichever is earlier ($0.2 million and $0.7 million); the non-cash amortization of the ENs and Royalty-Linked Notes ($0.6 million and $2.9 million); and the non-cash adjustments to the fair value of derivatives ($15.8 million and $74.3 million) for the three and six months ended June 30, 2021, respectively, and 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 ($0.8 million and $1.5 million); the non-cash amortization of the ENs and Royalty-Linked Notes ($2.9 million and $4.5 million); one-time, non-capitalized financing transaction costs ($0.0 million and $2.1 million) and the offsetting non-cash adjustments to the fair value of derivatives ($0.0 million and $1.7 million) for the three and six months ended June 30, 2020, respectively.

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, netincome/(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 income/(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 and six months ended June 30, 2021 and June 30, 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 income/(loss) and non-GAAP net loss per share to GAAP net income/(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 planned interactions and communications with the FDA, the Company's expectations with regard to its ability to resolve the matters set forth in the CRL and obtain approval for oral sulopenem, the conduct of potential future clinical and non-clinical development of sulopenem, the potential timing for resuming pre-commercialization activities, and the sufficiency of the Company's cash resources. 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 uncertainties inherent in the initiation and conduct of clinical and non-clinical development, including any potential additional clinical trials and non-clinical development that may be conducted in response to the CRL, availability and timing of data from such potential clinical and non-clinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, including any potential resubmission of the NDA, 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 August 13, 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.

Investor Contact:
Judy Matthews
Chief Financial Officer
312-778-6073
IR@iterumtx.com