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): July 26, 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 8.01. Other Events.

On July 26, 2021, Iterum Therapeutics plc issued a press release announcing that it had received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for sulopenem etzadroxil/probenecid for the treatment of uncomplicated urinary tract infections in patients with a quinolone non-susceptible pathogen. The CRL provided that the FDA has completed its review of the NDA and has determined that it cannot approve the NDA in its present form.

The full text of the press release issued in connection with this announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Iterum Therapeutics plc dated July 26, 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: July 26, 2021

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

EXHIBIT 99.1

Iterum Therapeutics Receives Complete Response Letter from U.S. Food and Drug Administration for Oral Sulopenem

DUBLIN, Ireland and CHICAGO; July 26, 2021 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (the "Company"), 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 announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for sulopenem etzadroxil/probenecid (oral sulopenem) on July 23, 2021. The CRL provided that the FDA has completed its review of the NDA and has determined that it cannot approve the NDA in its present form.

In the CRL, the FDA acknowledged that the Phase 3 SURE-1 clinical trial demonstrated statistical significance in difference in overall response rate of oral sulopenem compared to ciprofloxacin in the ciprofloxacin-resistant population. However, the FDA determined that additional data are necessary to support approval for the treatment of adult women with uncomplicated urinary tract infections caused by designated susceptible microorganisms proven or strongly suspected to be non-susceptible to a quinolone. The FDA recommended that Iterum conduct at least one additional adequate and well-controlled clinical trial, potentially using a different comparator drug. Additionally, the FDA recommended that Iterum conduct further nonclinical investigation to determine the optimal dosing regimen, although the FDA stated that this recommendation does not raise an approvability issue. The FDA indicated its willingness to work with Iterum on the design of the clinical trial(s) to address the deficiencies noted.

There were no chemistry, manufacturing or controls (CMC) issues identified in the CRL, nor were there any safety issues found in over 1,800 patients treated with sulopenem across the Company's clinical development program.

"We are disappointed in this outcome and believe that the data package submitted was adequate for the approval of oral sulopenem," said Corey Fishman, Chief Executive Officer. "Regardless, we will evaluate the points raised in the CRL for discussion with the FDA to determine an expeditious path forward. We remain confident in the value of, and unmet medical need for, oral sulopenem to treat multi-drug resistant infections, including fast-growing quinolone non-susceptible pathogens."

Iterum intends to review the CRL with its advisors and plans to request a Type A meeting in the coming weeks. Following the Type A meeting, anticipated to be late in the third quarter, Iterum expects to provide an update on next steps as to the potential additional clinical and non-clinical work to be done prior to a resubmission of the NDA for approval of oral sulopenem.

Iterum notes that cash, cash equivalents and short-term investments were $100.5 million at the end of the first quarter of 2021. Based on the current operating plan and subject to final determination of the design and planned conduct of additional clinical and potential nonclinical development for sulopenem, the Company believes that it is well positioned financially to fund its operations into the second half of 2023.

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 an oral formulation and IV formulation. 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.

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 future clinical and potential nonclinical development of sulopenem 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 nonclinical development, including any additional trials that may be conducted in response to the CRL, availability and timing of data from such clinical and nonclinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, including any 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 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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