**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 1, 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 1, 2021, Iterum Therapeutics plc (the "Company") issued a press release announcing that it had received a letter from the U.S. Food and Drug Administration ("FDA") stating that, as part of their ongoing review of the Company's New Drug Application for sulopenem etzadroxil/probenecid, the agency has identified deficiencies that preclude the continuation of the discussion of labeling and post marketing requirements/commitments at this time. No details with respect to deficiencies were disclosed by the FDA in this notification and the letter further states that the notification does not reflect a final decision on the information under review.

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 1, 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 2, 2021

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

**EXHIBIT 99.1**

# Iterum Therapeutics Provides Regulatory Update

DUBLIN, Ireland and CHICAGO; July 01, 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 the Company received a letter from the U.S. Food and Drug Administration ("FDA") stating that, as part of their ongoing review of the Company's New Drug Application ("NDA") for sulopenem etzadroxil/probenecid, the agency has identified deficiencies that preclude the continuation of the discussion of labeling and post marketing requirements/commitments at this time.
No details with respect to deficiencies were disclosed by the FDA in this notification and the letter further states that the notification does not reflect a final decision on the information under review. In a letter to the Company dated January 21, 2021, the FDA had assigned a Prescription Drug User Fee Act ("PDUFA") goal date of July 25, 2021 for completion of its review of the NDA.

The Company intends to work with the FDA to understand the nature of the deficiencies and resolve them as quickly as possible.

"While we are disappointed by this news, we continue to believe in the potential of sulopenem to help address the growing challenge of antibiotic resistance" said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. "Our goal now is to work with the FDA to identify and resolve the issues as expeditiously as possible in order to continue advancing this much needed antibiotic".

**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. The NDA for sulopenem etzadroxil/probenecid for the treatment of uncomplicated urinary tract infections in patients with a quinolone non-susceptible pathogen has been accepted for review by the FDA and a PDUFA goal date of July 25, 2021 has been assigned to it.

**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 NDA, the Company's expectations with regard to its interactions and communications with the FDA and the Company's expectations with regard to its ability address any deficiencies the FDA may identify. 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 Annual 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.

**Investor Contact:**
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