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 11, 2022

Iterum Therapeutics plc

(Exact name of Registrant as Specified in Its Charter)

Ireland	**001-38503**	**Not applicable**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
Fitzwilliam Court 1st Floor Leeson Close Dublin 2, Ireland **(Address of Principal Executive Offices)**		**Not applicable** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: +353 1 6694820

(Former Name or Former Address, if Changed Since Last Report)

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:

☐ 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(s)**	**Name of each exchange on which registered**
Ordinary Shares, par value $0.01 per share	ITRM	The NASDAQ Stock Market LLC

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 11, 2022, Iterum Therapeutics plc (the "Company") issued a press release announcing that it has reached an agreement with the U.S. Food and Drug Administration ("FDA") under the special protocol assessment ("SPA") process on the design, endpoints and statistical analysis of a Phase 3 clinical trial for oral sulopenem etzadroxil-probenecid ("oral sulopenem") for the treatment of uncomplicated urinary tract infections. The SPA agreement provides that the design and planned analysis of the trial, as set out in the protocol submitted to the FDA, adequately addresses the objectives necessary to support the potential resubmission of the Company's new drug application for oral sulopenem.

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 11, 2022
104 Cover Page Interactive Data File (embedded within the Inline XBRL document

SIGNATURES

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

Iterum Therapeutics plc

Date: July 11, 2022

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

Iterum Therapeutics Announces Special Protocol Assessment (SPA) Agreement With the FDA

--SPA supports protocol for Phase 3 Clinical Trial of Oral Sulopenem for the treatment of Uncomplicated Urinary Tract Infections--

--Clinical Trial Expected to Begin Enrollment in Q4 2022--

DUBLIN, Ireland and CHICAGO; July 11, 2022 (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, announced today that it has reached an agreement with the U.S. Food and Drug Administration ("FDA") under the special protocol assessment ("SPA") process on the design, endpoints and statistical analysis of a Phase 3 clinical trial for oral sulopenem etzadroxil-probenecid ("oral sulopenem") for the treatment of uncomplicated urinary tract infections ("uUTI"). The SPA agreement provides that the design and planned analysis of the trial, as set out in the protocol submitted to the FDA, adequately addresses the objectives necessary to support the potential resubmission of the Company's new drug application ("NDA") for oral sulopenem.

"We are pleased to have concluded discussions with the FDA and reached agreement on key elements of the trial design to support the potential resubmission of the NDA for oral sulopenem for uUTI under the SPA process," said Corey Fishman, Chief Executive Officer. "The SPA underscores our alignment with the FDA on important regulatory, clinical and scientific requirements for our planned Phase 3 trial in uUTI and reflects our ongoing commitment to bring this important therapy to market. We are excited about this important milestone and are looking forward to starting recruitment for this trial as soon as possible."

The pivotal study to be conducted pursuant to the SPA agreement is designed as a non-inferiority trial comparing oral sulopenem and Augmentin ® (amoxicillin/clavulanate) and is entitled "A prospective, Phase 3, randomized, multi-center, double-blind study of the efficacy, tolerability, and safety of oral sulopenem etzadroxil/probenecid versus oral amoxicillin/clavulanate for treatment of uncomplicated urinary tract infections (uUTI) in adult women." Patients will be randomized to receive either oral sulopenem twice daily for 5 days or Augmentin® (amoxicillin/clavulanate) twice daily for 5 days. The primary endpoint is the overall response (clinical and microbiologic combined response) at Day 12 of the study. The study is expected to enroll approximately 1,966 patients and is anticipated to start enrolling in the fourth quarter of 2022. Study start-up activities have already been commenced by the Company to enable timely initiation and recruitment.

About Special Protocol Assessments

Under the SPA process, the FDA provides a clinical trial sponsor with an official evaluation and written guidance on the design of a proposed protocol intended to form the basis for an NDA. A SPA agreement indicates concurrence by the FDA with the adequacy and acceptability of specific critical elements of the overall protocol design for a clinical trial intended to support a future marketing application, but it does not indicate FDA concurrence on every protocol detail. A SPA agreement also does not ensure the receipt of marketing approval or that the approval process will be faster than conventional procedures. A determination regarding marketing approval is addressed during the review of a submitted NDA and depends on efficacy and safety results and an evaluation of the overall benefits and risks of treatment after review of the data from the development program in its totality.

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 Iterum's plans, strategies and prospects for its business, including the timing and conduct of planned clinical and non-clinical development of sulopenem to support a potential resubmission of the NDA for oral sulopenem and Iterum's expectations with regard to its ability to resolve the matters set forth in the complete response letter (CRL) received by Iterum in July 2021 and obtain approval for oral sulopenem. 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 Iterum'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 Iterum's control, including uncertainties inherent in the design, initiation and conduct of clinical and non-clinical development, including the planned additional clinical trial and non-clinical development conducted in response to the CRL, availability and timing of data from such clinical and non-clinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, including the potential resubmission of the NDA for oral sulopenem, 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 Iterum's expectations regarding how far into the future Iterum's cash on hand will fund Iterum's ongoing operations including completing potential additional clinical and non-clinical development of oral sulopenem, the impact of COVID-19 and related responsive measures thereto, Iterum's ability to maintain its listing on the Nasdaq Capital Market, risks and uncertainties concerning the outcome, impact, effects and results of Iterum'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 Iterum'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 13, 2022, and other documents filed with the SEC from time to time. Forward-looking statements represent Iterum's beliefs and assumptions only as of the date of this press release. Except as required by law, Iterum 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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