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): June 1, 2020

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, Dublin 2, Ireland		**Not Applicable**
(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(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 June 1, 2020, the Company issued a press release announcing topline results for its Phase 3 clinical trial of oral and IV sulopenem in complicated urinary tract infection, including that the clinical trial did not meet its primary endpoint, and that the Company is evaluating its corporate, strategic and financial alternatives.

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, dated June 1, 2020, of Iterum Therapeutics plc

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.

Dated: June 2, 2020

Iterum Therapeutics plc

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

Exhibit 99.1

Iterum Therapeutics Announces Topline Results for a Phase 3 Clinical Trial of Oral and IV Sulopenem in Complicated Urinary Tract Infection

Study did not meet its primary endpoint

DUBLIN, Ireland and CHICAGO, June 01, 2020 — 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 announced that sulopenem did not achieve statistical non-inferiority relative to ertapenem in its **SU**lopenem for **R**esistant **E**nterobacteriaceae (SURE) 2 clinical trial in complicated urinary tract infection (cUTI).

The primary U.S. Food and Drug Administration (FDA) endpoint was overall clinical and microbiologic response on Day 21 in the micro-MITT population as evaluated using a 10% non-inferiority margin.

The randomized, multi-center, double-blind SURE 2 clinical trial enrolled 1,395 patients to measure the efficacy, tolerability, and safety of IV and oral sulopenem for the treatment of cUTI in adults. Patients were randomized to receive either IV sulopenem once daily for a minimum of five days followed by oral sulopenem twice daily to complete seven to ten days of treatment, or IV ertapenem once daily for a minimum of five days followed by either oral ciprofloxacin or, for quinolone resistant isolates, amoxicillin-clavulanate twice daily. Responder rates at the test of cure visit for sulopenem were 67.8% (301 of 444 patients) and for ertapenem were 73.9% (325 of 440 patients) with a difference of -6.1% (95% confidence interval (CI): -12.0%, -0.1%). The difference in response rates was driven almost entirely by higher rates of asymptomatic bacteriuria on sulopenem relative to ertapenem, only evident at the test of cure visit; the rates of patients receiving additional antibiotics or with residual cUTI symptoms was similar. Clinical response at the test of cure in the Modified Intent to Treat patient population (sulopenem vs ertapenem: 2.0% (95% CI: -1.5, 5.4%) and Clinically Evaluable patient population (sulopenem vs ertapenem: 0.4% (95% CI: -2.6%, 3.5%) was similar. The outcome at other secondary endpoints was also similar, including the overall response at the end of therapy visit at Day 10, (sulopenem: 385 of 444 patients (86.7%); ertapenem: 391 of 440 patients (88.9%).

“We are very disappointed by the outcome in the cUTI study, although sulopenem was well tolerated and demonstrated a safety profile consistent with previous studies and the penem class in general,” said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. Based on these trial results, Iterum Therapeutics is evaluating its corporate, strategic and financial alternatives with the goal of maximizing value for its stakeholders while prudently managing its remaining resources. These alternatives could potentially include the licensing, sale or divestiture of the company’s assets or proprietary technologies, a sale of the company, a merger or other business combination, another strategic transaction involving the company, restructuring activities, winding down of operations, dissolving and liquidating assets or seeking protection under bankruptcy laws. The evaluation of corporate, strategic and financial alternatives may not result in any particular action or any transaction being pursued, entered into or consummated, and there is no assurance as to the timing, sequence or outcome of any action or transaction or series of actions or transactions.

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. The safety profile of IV sulopenem has been documented in a Phase 2 program. Given these results, Iterum Therapeutics initiated three pivotal Phase 3 clinical trials of oral and IV sulopenem for uncomplicated urinary tract infections, complicated urinary tract infections and complicated intra-abdominal infections.

The FDA has granted Special Protocol Agreements (SPA) and Qualified Infectious Disease Product (QIDP) designations for oral and IV sulopenem in accordance with the Generating Antibiotics Incentives Now (GAIN) Act, which allow for five years of additional regulatory exclusivity and expedited Fast Track FDA review.

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. 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.

Forward-looking Statements

This press release contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding the development, therapeutic and market potential of sulopenem and our evaluation of corporate, strategic and financial alternatives. 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,” “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 our 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 our control, including the uncertainties inherent in the conduct of clinical trials, availability and timing of data from clinical trials, changes in regulatory requirements or decisions of regulatory authorities, changes in public policy or legislation, commercialization plans and timelines, if approved, the actions of third-party clinical research organizations, suppliers and manufacturers, the accuracy of our expectations regarding how far into the future our cash on hand will fund our ongoing operations, the sufficiency of our cash resources and our ability to continue as a going concern, the impact of COVID-19 and related responsive measures thereto, risks and uncertainties concerning the outcome, impact, effects and results of our evaluation of corporate, strategic and financial alternatives, including the terms, timing, structure, value, benefits and costs of any corporate, strategic or financial alternative and our ability to complete one at all, risks and uncertainties related to the impact of this announcement on our business, financial condition, results of operations and the price of our securities and other factors discussed under the caption “Risk Factors” in its most recently filed Quarterly

Report on Form 10-Q, and other documents filed with the SEC from time to time. Forward-looking statements represent our beliefs and assumptions only as of the date of this press release. Except as required by law, we assume 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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