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 29, 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	
(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))

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).

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	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 29, 2020, Iterum Therapeutics plc, or the Company, issued a press release announcing topline results from its Phase 3 clinical trial of oral sulopenem in uncomplicated urinary tract infection, including that oral sulopenem demonstrated superiority in treatment of patients with quinolone resistant pathogens, and that the Company is evaluating its corporate, organizational, strategic, financial and financing 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 29, 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.

Iterum Therapeutics plc

Dated: June 29, 2020

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

EXHIBIT 99.1

Iterum Therapeutics Announces Topline Results from its Phase 3 Clinical Trial of Oral Sulopenem for the Treatment of Uncomplicated Urinary Tract Infections

Sulopenem demonstrates superiority in treatment of patients with quinolone resistant pathogens

Company to discuss NDA filing with FDA

DUBLIN, Ireland and CHICAGO, June 29, 2020 -- Iterum Therapeutics plc (Nasdaq: ITRM), a clinical-stage pharmaceutical company focused on developing next generation oral antibiotics to treat infections caused by multi-drug resistant pathogens in community settings, today announced topline results from its **Su**lopenem for **R**esistant **E**nterobacteriaceae (SURE) 1 clinical trial for the treatment of Uncomplicated Urinary Tract Infections (uUTI). Sulopenem is a novel anti-infective compound that, if approved, would be the first penem antibiotic with an oral formulation indicated for treatment of uUTI.

In SURE1, there were two independent primary endpoints, with achievement of either of those endpoints expected to provide a potential path to marketing approval based on previous discussions with the U.S. Food and Drug Administration (FDA). In the population of patients with baseline pathogens resistant to quinolones, sulopenem achieved the related primary endpoint by demonstrating superiority to ciprofloxacin, providing substantial evidence of a treatment effect in patients with uUTI. With a p-value of <0.001, this result was highly statistically significant. In the second population of patients with organisms susceptible to quinolones, sulopenem was not non-inferior to ciprofloxacin and did not achieve the related primary endpoint, with the difference in outcomes driven by the rate of asymptomatic bacteriuria post treatment. In SURE1, sulopenem was well tolerated with a favorable safety profile, consistent with the SURE2 and SURE3 trials.

“We are extremely pleased to have a potential path to approval for sulopenem in uUTI. Approximately 5-6 million urinary tract infections in the U.S. every year are caused by quinolone resistant pathogens. If approved, sulopenem would provide a treatment option for women with infections due to these resistant pathogens,” said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. “Sulopenem is the first new oral antibiotic to demonstrate success in treating uUTIs in a phase 3 trial in over twenty years.” Mr. Fishman continued, “We anticipate a pre-NDA meeting with the FDA in the third quarter of 2020 to discuss a path forward.”

Michael Dunne, M.D., Chief Scientific Officer of Iterum Therapeutics, stated, “Superiority trials to define the effectiveness of novel antibacterial agents are rarely performed but remain the ultimate test for defining the value of a new agent in an area of high unmet medical need. Sulopenem has demonstrated efficacy in the treatment of UTI due to a quinolone resistant organism, a scenario found in almost 30% of all urinary tract infections in women in the United States today.”

The randomized, multi-center, double-blind SURE1 clinical trial enrolled 1,670 patients to measure efficacy, tolerability, and safety of oral sulopenem/probenecid for the treatment of uUTI in adult women. Patients were randomized to receive either oral sulopenem/probenecid twice daily for five days of treatment, or oral ciprofloxacin twice daily for three days of treatment. The End of Treatment (EOT) visit occurred on Day 5 and the Test of Cure Visit (TOC) at Day 12. Two independent populations were prespecified and tested for an overall response of success

at the TOC: a quinolone resistant population being assessed for superiority, defined as a p value <0.05, and a quinolone susceptible population being tested for non-inferiority, based on the lower limit of the 95% confidence interval (CI) for the difference in the microbiologic-modified intent to treat population being greater than -10%. A prespecified analysis of the outcome in both susceptible and non-susceptible patients combined was also performed to describe the overall results of treatment of uUTI with sulopenem relative to ciprofloxacin. The following table sets forth the topline results from the trial.

Micro-MITT population	Sulopenem n/N (%)	Ciprofloxacin n/N (%)	Difference (%) (95% CI)	P value
Quinolone Non-susceptible Population				
Overall Response (TOC)	**92/147 (62.6%)**	**50/139 (36.0%)**	**26.6% (15.1, 37.4)**	**< 0.001**
Reason for Failure: Asymptomatic bacteriuria	27 (18.4%)	38 (27.3%)		
Clinical Response (TOC)	122/147 (83.0%)	87/139 (62.6%)	20.4% (10.2, 30.4)	< 0.001
Overall Response (EOT)	95/147 (64.6%)	42/139 (30.2%)	34.4% (23.1, 44.8)	< 0.001
Quinolone Susceptible Population				
Overall Response (TOC)	**247/370 (66.8%)**	**326/415 (78.6%)**	**-11.8% (-18.0, -5.6)**	
Reason for Failure: Asymptomatic bacteriuria	47 (12.7%)	16 (3.9%)		
Clinical Response (TOC)	300/370 (81.1%)	349/415 (84.1%)	-3.0% (-8.4, 2.3)	
Overall Response (EOT)	240/370 (64.9%)	271/415 (65.3%)	-0.4% (-7.1, 6.2)	
Combined (Quinolone Susceptible and Quinolone Non-susceptible Populations)				
Overall Response (TOC)	**339/517 (65.6%)**	**376/554 (67.9%)**	**-2.3% (-7.9, 3.3)**	
Reason for Failure: Asymptomatic bacteriuria	74 (14.3%)	54 (9.7%)		
Clinical Response (TOC)	422/517 (81.6%)	436/554 (78.7%)	2.9% (-1.9, 7.7)	
Overall Response (EOT)	335/517 (64.8%)	313/554 (56.5%)	8.3% (2.4, 14.1)	

“The difference in the overall response to treatment in the population of patients with a quinolone susceptible baseline pathogen was driven to a large degree by a greater amount of asymptomatic bacteriuria in the sulopenem treated patients relative to those receiving ciprofloxacin,” observed Dr. Dunne. ““This same finding was observed in the recently completed Phase 3 clinical trial of sulopenem in complicated urinary tract infections, SURE2. In that study, the difference in outcome between ertapenem and sulopenem was driven largely by the post therapy rate of asymptomatic bacteriuria and, notably, was lower only in those patients who received ertapenem followed by ciprofloxacin and not in any other pairwise comparison with sulopenem or ertapenem treated patients. The clinical significance of post treatment asymptomatic bacteriuria and its relationship to oral dosing with ciprofloxacin will be the focus of additional investigation.”

In the safety population of 1,660 patients, treatment related adverse events were observed in 11.4% and 11.9% of patients on sulopenem and ciprofloxacin, respectively. The most commonly reported adverse events were diarrhea, 7.3% and 7.6%, nausea, 3.4% and 4.0%, and headache 2.2% and 2.2%, for sulopenem and ciprofloxacin patients, respectively. Discontinuations due to adverse events were uncommon on both regimens and were seen in 1.1% of patients on sulopenem and 1.5% of patients on ciprofloxacin. Serious adverse events

(SAE) were seen in 0.6% of patients on sulopenem with no drug-related SAE and 0.4% of patients on ciprofloxacin with one drug-related SAE.

Based on these trial results, the Company plans to request a pre-NDA meeting with the FDA to discuss its filing strategy. In parallel, the Company is also evaluating its corporate, organizational, strategic, financial and financing alternatives with the goal of maximizing value for its stakeholders, while prudently managing its resources.

About Urinary Tract Infections

UTIs result in 13.5 million office or emergency room visits and 21 million prescriptions in the U.S. annually. According to the U.S. Centers for Disease Control and Prevention (CDC), multidrug resistant *Escherichia coli*, the cause of many serious infections, including UTIs, are a growing concern in the U.S. where at least two million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of these infections. The effectiveness of common antibiotics used to treat UTIs has decreased, with approximately one-third of medications prescribed for UTIs failing, including fluoroquinolones, penicillins, and cephalosporins. Patients who are elderly, female or diagnosed with diabetes are at an elevated risk for UTIs and for uUTIs resistant to commonly used antibiotics. Fifty to sixty percent of women are likely to be affected by a UTI in their lifetime, and nearly 30 percent will suffer a recurrence.

About Sulopenem

Sulopenem, a novel oral penem anti-infective compound, has demonstrated potent *in vitro* activity against a wide variety of gram-negative, gram-positive and anaerobic bacteria resistant to other antibiotics. If approved, sulopenem would help address the significant clinical and economic need for new oral antibiotics that enable the avoidance of hospitalization. The safety profile of IV sulopenem has been previously documented in a Phase 2 program. Given these results, oral sulopenem is being evaluated in this Phase 3 clinical trial for uncomplicated urinary tract infections.

The U.S. Food and Drug Administration (FDA) has granted Special Protocol Agreements (SPA) and Qualified Infectious Disease Product (QIDP) designations for sulopenem in accordance with the Generating Antibiotics Incentives Now (GAIN) Act, which provides 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. Iterum Therapeutics is advancing its first compound, sulopenem, a novel penem anti-infective compound, in Phase 3 clinical development with an oral 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. 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, our expectations regarding a potential path forward for marketing approval of sulopenem for uUTI and with respect to the overall regulatory process and our evaluation of corporate, organizational, strategic and financial and financing 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,” “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 Therapeutics’ 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 Therapeutics’ 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 Company’s ability to apply for regulatory approval, changes in public policy or legislation, commercialization plans and timelines, if sulopenem is 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 the Company’s evaluation of corporate, organizational, strategic, financial and financing alternatives, including the terms, timing, structure, value, benefits and costs of any corporate, organizational, strategic, financial or financing alternative and the Company’s ability to complete one at all, risks and uncertainties related to the impact of this announcement on the Company’s business, financial condition, results of operations and the price of the Company’s 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 Iterum Therapeutics’ beliefs and assumptions only as of the date of this press release. Except as required by law, Iterum Therapeutics 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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