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): May 14, 2019

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:

☐ 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).

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. ☒

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, $0.01 par value per share	ITRM	The Nasdaq Stock Market LLC

Item 2.02. Results of Operations and Financial Condition.

On May 14, 2019, Iterum Therapeutics plc issued a press release announcing certain financial results for its first quarter ended March 31, 2019. A copy of the press release is furnished herewith as Exhibit 99.1.

The information in this current report on Form 8-K, including the press release attached as Exhibit 99.1 hereto, is being furnished, but shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Iterum, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Iterum Therapeutics plc, dated May 14, 2019

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: May 14, 2019

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

Iterum Therapeutics Reports First Quarter 2019 Financial Results

On track to complete enrollment in all three Phase 3 clinical trials before year-end

Filed patent application that may extend Iterum's intellectual property rights into the 2040s

DUBLIN, Ireland and CHICAGO, May 14, 2019 -- Iterum Therapeutics plc (Nasdaq: ITRM), a clinical-stage pharmaceutical company developing anti-infectives against multi-drug resistant pathogens, today reported financial results for the first quarter ended March 31, 2019.

"The first quarter of 2019 was highlighted by the U.S. Food and Drug Administration (FDA) granting us Qualified Infectious Disease Product (QIDP) status in four new indications, as well as Fast Track designation for all seven potential indications of oral and IV sulopenem for which QIDP status has been received," said Corey Fishman, Chief Executive Officer of Iterum Therapeutics plc. "We remain focused on completing enrollment of all three of our ongoing Phase 3 clinical trials this year. A new effective oral therapy in our studied indications has become critical due to the rise in multi-drug resistant infections in the community, and we are excited to be at the forefront of seeking to provide a near-term solution."

Q1 2019 Highlights and Recent Events

- **FDA granted QIDP designation and Fast Track:** In the first quarter, oral sulopenem and sulopenem IV received QIDP designation in four new indications: community-acquired bacterial pneumonia, acute bacterial prostatitis, gonococcal urethritis, and pelvic inflammatory disease. These indications, as well as the three indications currently in Phase 3 development, also received Fast Track designation from the FDA.
- **Based on current enrollment rates, all three Phase 3 clinical trials are on track to complete enrollment before year-end; sample size adjustment review underway for uncomplicated urinary tract infection (uUTI) study:** Based on current enrollment rates, all three Phase 3 clinical trials are on track to complete enrollment before year-end. Enrollment in the uUTI study has passed the 1/3 target level and this triggers the first of two pre-planned analyses relating to potential sample size adjustments. The results of this analysis are expected to be available around the end of Q2.
- **Presented data showing that mismatched empiric antibiotic therapy leads to double the rate of hospitalization for a uUTI**: As presented at the 29th European Congress of Clinical Microbiology and Infectious Diseases in April 2019, culture data shows that age, gender, Diabetes mellitus and prior resistance to antibiotics increased the likelihood of treatment

failure, and that hospitalization rates doubled to over 15% for patients whose pathogens were not susceptible to the antibiotic they received.

- **Filed a non-provisional patent application with United States Patent and Trademark Office:** The extensive pharmacokinetic work supporting the sulopenem program demonstrated that plasma levels of sulopenem after multiple days of oral dosing when combined with probenecid remained at or above the concentrations on Day 1, relative to dosing with oral sulopenem alone, enhancing its potential antimicrobial effect. If granted, this method of use patent on the combination of sulopenem and probenecid would provide 20 years of intellectual property protection. The current U.S. composition of matter patent on sulopenem etzadroxil expires in 2029 with potential extension to 2034 under the Hatch-Waxman Act.

Upcoming Scientific and Investor Presentations

- Corporate presentation at the RBC Capital Markets Global Healthcare Conference on Tuesday, May 21, 2019, in New York, New York
- Multiple scientific presentations at American Society of Microbiology (ASM) Microbe 2019 from June 20-24, 2019, in San Francisco, California

First Quarter 2019 Financial Results

As of March 31, 2019 , Iterum had cash, cash equivalents and short-term investments of $69.6 million and approximately 14.4 million shares outstanding. Iterum expects that its cash, cash equivalents and short-term investments, along with its available borrowings, will be sufficient to fund operations into 2020.

Research and development (R&D) expenses for the first quarter of 2019 were $17.4 million compared to $10.9 million for the same period in 2018. The increase was primarily due to higher clinical trial expenses associated with the three Phase 3 clinical trials initiated in the third quarter of 2018.

General and administrative (G&A) expenses for the first quarter of 2019 were $3.1 million compared to $1.5 million for the same period in 2018. The increase was primarily due to increased costs associated with operating as a public company, additional headcount to support business activities, and increased marketing and market research expenses.

For the first quarter of 2019, Iterum reported a net loss of $20.6 million compared to a net loss of $12.1 million for the same period in 2018.

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. If approved, sulopenem will help address the significant clinical and economic need for new oral antibiotics that enable the effective treatment of resistant pathogens in the community, make possible the avoidance of hospitalization, and facilitate early hospital discharge by providing continuity-of-care step-down therapy. The safety

profile of IV sulopenem has been documented in a Phase 2 program. Oral and IV sulopenem are being evaluated in three pivotal Phase 3 clinical trials for uncomplicated urinary tract infections, complicated urinary tract infections, and complicated intra-abdominal infections.

Probenecid, which is being co-administered with sulopenem in a bilayer tablet, is approved as an adjuvant to therapy for elevation and prolongation of plasma levels of β-lactam compounds including penicillin, ampicillin, methicillin, oxacillin, cloxacillin, and nafcillin.

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 oral and IV formulations. 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 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 expectations about future revenue, expenses, cash flows and net income or loss, the sufficiency of cash resources, the granting or issuing of patents, the development, therapeutic and market potential of sulopenem, and the timing, progress and results of clinical trials. 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 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, clinical trial patient enrollment, availability and timing of data from clinical trials, changes in regulatory requirements or decisions of regulatory authorities, commercialization plans and timelines, if approved, the actions of third-party clinical research organizations, suppliers and manufacturers 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, 2019, 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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ITERUM THERAPEUTICS PLC
Condensed Consolidated Statement of Operations
(In thousands except share and per share data)
(Unaudited)

	Three months ended March 31,	
	2019	**2018**
Revenue	$ 37	$ 191
Operating expenses:		
Research and development	(17,387)	(10,879)
General and administrative	(3,116)	(1,515)
Total operating expenses	(20,503)	(12,394)
Operating loss	(20,466)	(12,203)
Interest (expense) / income, net	(104)	85
Other income, net	124	61
Income tax expense	(134)	(89)
Net loss attributable to ordinary shareholders	$ (20,580)	$ (12,146)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (1.44)	$ (61.36)
Weighted average ordinary shares outstanding – basic and diluted	14,290,437	197,949

ITERUM THERAPEUTICS PLC
Condensed Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	March 31, 2019	**December 31, 2018**
Cash, cash equivalents, restricted cash and short-term investments	$ 69,600	$ 84,551
Other assets	19,534	13,320
Total assets	**$ 89,134**	**$ 97,871**
Long-term debt, less current portion	12,139	13,079
Other liabilities	25,365	13,170
Total liabilities	$ 37,504	$ 26,249
Total shareholders' equity	51,630	71,622
Total liabilities and shareholders' equity	**$ 89,134**	**$ 97,871**