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, 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 2.02. Results of Operations and Financial Condition.

On May 14, 2020 Iterum Therapeutics plc issued a press release announcing its financial results for the first quarter ended March 31, 2020. 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.

Non-GAAP Financial Measures

To supplement Iterum Therapeutics' financial results presented in accordance with U.S. generally accepted accounting principles, or GAAP, Iterum Therapeutics presents non-GAAP adjusted net loss (and the related per share measure) to exclude from reported GAAP net loss (and the related per share measure) for the first quarter ended March 31, 2020, the interest expense associated with accrued interest on the Exchangeable Notes (ENs) payable in cash, shares or a combination of both upon redemption or in cash at January 31, 2025 (the maturity date), whichever is earlier ($0.652 million) and the non-cash amortization of the ENs and Royalty-Linked Notes ($1.613 million); one-time, non-capitalized private placement transaction costs ($2.130 million); and the offsetting non-cash adjustments to the fair value of derivatives ($1.679 million). Iterum Therapeutics believes that the presentation of non-GAAP adjusted net loss, when viewed with its results under GAAP and the accompanying reconciliation, provides useful supplementary information to, and facilitates additional analysis by, investors, analysts, and Iterum Therapeutics' management in assessing Iterum Therapeutics' performance and results from period to period. This non-GAAP measure closely aligns with the way management measures and evaluates Iterum Therapeutics' performance. This non-GAAP financial measure should be considered in addition to, and not a substitute for, or superior to, net loss or other financial measures calculated in accordance with GAAP. Non-GAAP adjusted net loss is not based on any standardized methodology prescribed by GAAP and represents GAAP net loss, which is the most directly comparable GAAP measure, adjusted to exclude the interest expense associated with accrued interest on the Exchangeable Notes (ENs) payable in cash, shares or a combination of both upon redemption or in cash at January 31, 2025 (the maturity date), whichever is earlier ($0.652 million) and the non-cash amortization of the ENs and Royalty-Linked Notes ($1.613 million); one-time, non-capitalized private placement transaction costs ($2.130 million); and the offsetting non-cash adjustments to the fair value of derivatives ($1.679 million) for the first quarter ended March 31, 2020. Because of the non-standardized definitions of non-GAAP financial measures, Non-GAAP adjusted net loss used by Iterum Therapeutics in the accompanying press release and tables therein has limits in its usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies. A reconciliation of non-GAAP adjusted net loss to GAAP net loss has been provided in the tables included in the accompanying press release.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Iterum Therapeutics plc dated May 14, 2020

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, 2020

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

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

Iterum Therapeutics Reports First Quarter 2020 Financial Results

--Phase 3 topline results from sulopenem clinical trials in uUTI and cUTI expected Q2 --

-- Raised $51.6 million through a private placement with new and existing investors --

DUBLIN, Ireland and CHICAGO, May 14, 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 reported financial results for the first quarter ended March 31, 2020.

"During this challenging time, it is more important than ever to avoid hospitalization. We believe sulopenem, as potentially the first and only oral and IV penem antibiotic, will provide physicians the confidence and flexibility to treat their patients in a community setting. Should hospitalization be required, sulopenem can also be used as a step-down therapy allowing patients to leave the hospital sooner thereby reducing the risk of hospital-acquired infections, which is a benefit for patients, their families, and the over-stressed healthcare system," said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. "We expect to share topline results from our complicated urinary tract infection (cUTI) trial this month and topline results from our uncomplicated urinary tract infection (uUTI) trial shortly thereafter within the second quarter."

Q1 2020 Highlights and Upcoming Events

- **Strengthened the balance sheet**: Iterum raised approximately $51.6 million ($46.7 million net of fees and expenses) in January 2020 through a private placement of units comprised of approximately (i) $51.6 million aggregate principal amount of its 6.500% exchangeable senior subordinated notes due 2025 and (ii) $0.1 million aggregate principal amount of its limited recourse royalty-linked senior subordinated notes.

- **Phase 3 topline results from cUTI and uUTI studies are expected in the second quarter**: Iterum is in the final stages of data processing and analysis of the clinical study data.

Upcoming Investor Presentation

- Virtual corporate presentation at the RBC Capital Markets Global Healthcare Conference on Wednesday, May 20, 2020 at 10:20-10:45am ET.

First Quarter 2020 Financial Results

As of March 31, 2020 , Iterum had cash and cash equivalents of $23.3 million and approximately 14.9 million shares outstanding. Iterum expects that its current cash and cash equivalents will be sufficient to fund its operations into the second half of 2020.

Research and development (R&D) expenses for the first quarter of 2020 were $9.7 million compared to $17.4 million for the same period in 2019. The decrease was primarily due to reduced clinical trial expenses associated with the near completion of our Phase 3 clinical trials in the first quarter of 2020.

General and administrative (G&A) expenses for the first quarter of 2020 were $3.2 million compared to $3.1 million for the same period in 2019.

Other expenses for the first quarter of 2020 were $3.1 million compared to $0.0 million for the same period in 2019. The increase was primarily due to interest and other costs associated with the January 2020 private placement.

For the first quarter of 2020, Iterum reported a net loss of $16.1 million compared to a net loss of $20.6 million for the same period in 2019.

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 avoidance of hospitalization or 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 pivotal Phase 3 clinical trials of uncomplicated urinary tract infections, complicated urinary tract infections and complicated intra-abdominal infections.

The U.S. Food and Drug Administration (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 will provide 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 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 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 expectations about future revenue, expenses, cash flows and net income or loss, the sufficiency of cash resources, the development, therapeutic and market potential of sulopenem, and the timing, progress and results of clinical trials and regulatory submissions. 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 and other factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the “SEC”) on May 14, 2020, 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.

Investor Contact:
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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,	
	2020	**2019**
Revenue	$ —	$ 37
Operating expenses:		
Research and development	(9,743)	(17,387)
General and administrative	(3,151)	(3,116)
Total operating expenses	(12,894)	(20,503)
Operating loss	(12,894)	(20,466)
Interest expense, net	(2,596)	(104)
Private placement transaction costs	(2,130)	—
Adjustments to fair value of derivatives	1,679	—
Other (expense) / income, net	(38)	124
Total other (expense) / income	(3,085)	20
Income tax expense	(121)	(134)
Net loss attributable to ordinary shareholders	$ (16,100)	$ (20,560)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (1.08)	$ (1.44)
Weighted average ordinary shares outstanding – basic and diluted	14,868,973	14,290,437
Net loss - GAAP	(16,100)	(20,560)
Interest expense - accrued interest and amortization on Exchangeable Notes and Royalty-Linked Notes	2,267	-
Private placement transaction costs - not capitalized	2,130	-
Adjustments to fair value of derivatives	(1,679)	-
Non-GAAP adjusted loss	$ (13,382)	$ (20,560)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (1.08)	$ (1.44)
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.90)	$ (1.44)

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

	As of March 31, 2020	**As of December 31, 2019**
Cash and cash equivalents	$ 23,257	$ 4,801
Other assets	19,055	20,950
Total assets	**$ 42,312**	**$ 25,751**
Long-term debt, less current portion	$ 18,847	$ 7,625
Royalty-linked notes, less current portion	10,965	—
Derivative liability	25,359	—
Other liabilities	28,882	44,364
Total liabilities	84,053	51,989
Total shareholders' deficit	(41,741)	(26,238)
Total liabilities and shareholders' deficit	**$ 42,312**	**$ 25,751**