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): August 6, 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 August 6, 2020 Iterum Therapeutics plc issued a press release announcing its financial results for the second quarter ended June 30, 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 non-GAAP net loss per share to exclude from reported GAAP net loss and GAAP net loss per share for the three and six months ended June 30, 2020, the interest expense associated with accrued interest on the Exchangeable Notes (ENs) payable in cash, shares or a combination of both upon exchange, redemption or at January 31, 2025 (the maturity date), whichever is earlier ($0.827 million); the non-cash amortization of the ENs and Royalty-Linked Notes ($2.877 million) and the non-cash adjustments to the fair value of derivatives ($0.012 million) for the three months ended June 30, 2020, and the interest expense associated with accrued interest on the Exchangeable Notes (ENs) payable in cash, shares or a combination of both upon exchange, redemption or at January 31, 2025 (the maturity date), whichever is earlier ($1.479 million); the non-cash amortization of the ENs and Royalty-Linked Notes ($4.491 million); one-time, non-capitalized private placement transaction costs ($2.130 million); and the offsetting non-cash adjustments to the fair value of derivatives ($1.667 million) for the six months ended June 30, 2020.

Iterum Therapeutics believes that the presentation of non-GAAP adjusted net loss and non-GAAP net loss per share, 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. These non-GAAP financial measures closely align with the way management measures and evaluates Iterum Therapeutics' performance. These non-GAAP financial measures 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 and non-GAAP net loss per share are 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 exchange, redemption or at January 31, 2025 (the maturity date), whichever is earlier; the non-cash amortization of the ENs and Royalty-Linked Notes; one-time, non-capitalized private placement transaction costs and the non-cash adjustments to the fair value of derivatives for the three and six months ended June 30, 2020. Because of the non-standardized definitions of non-GAAP financial measures, Non-GAAP adjusted net loss and non-GAAP net loss per share 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 and non-GAAP net loss per share to GAAP net loss per share have 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 August 06, 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: August 6, 2020

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

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

Iterum Therapeutics Reports Second Quarter 2020 Financial Results

--Meeting with FDA Scheduled for end of Q3--

DUBLIN, Ireland and CHICAGO, August 6, 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 second quarter ended June 30, 2020.

"Based on data generated in our Phase 3 clinical program, we continue to believe that sulopenem can play a vital role in the treatment of infections caused by multi-drug resistant pathogens that have become prevalent in our community," said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. "We have been granted a meeting with the FDA at the end of the third quarter and plan to share the results of that meeting shortly thereafter."

Q2 2020 Highlights and Recent Events

- **Announced topline results in cUTI and uUTI Phase 3 trials and planning for a meeting with the FDA:** In June 2020, the Company announced that it achieved one of its two independent primary endpoints in the uncomplicated urinary tract infection (uUTI) trial by demonstrating superiority to ciprofloxacin in the treatment of patients with quinolone resistant pathogens. The Company also announced that sulopenem failed to achieve the primary endpoint in its complicated urinary tract infection (cUTI) trial. Based on these trial results and previous discussions with the U.S. Food and Drug Administration (FDA), the Company plans to discuss its potential regulatory filing options with the FDA in a meeting scheduled for the end of the third quarter.

- **Strengthened the balance sheet:** Raised $10.0 million gross proceeds ($8.7 million net of estimated fees and expenses) in two registered direct offerings to certain institutional investors of ordinary shares and concurrent private placements of warrants to purchase ordinary shares in June 2020 and July 2020.

- **Set record date for rights offering**: As previously disclosed, the Company established 5:00 p.m. on August 5, 2020, as the record date for its planned rights offering. The Company had agreed to undertake a rights offering of subscription rights to purchase additional units in connection with the Company's January 2020 private placement of units consisting of 6.500% Exchangeable Senior Subordinated Notes due 2025 and Limited Recourse Royalty-Linked Subordinated Notes.

Second Quarter 2020 Financial Results

As of June 30, 2020, the Company had cash and cash equivalents of $12.3 million and approximately 17.9 million shares outstanding. In July 2020, the Company received net proceeds of approximately $4.4 million from a registered direct offering of ordinary shares and concurrent private placement of warrants to purchase ordinary shares. The Company expects that its current cash and cash equivalents, including the proceeds from the July 2020 financing, will be sufficient to fund its operations into the fourth quarter of 2020. The Company is continuing to evaluate its corporate, organizational, strategic, financial and financing alternatives with the goal of maximizing value for its stakeholders, while prudently managing its resources.

Research and development (R&D) expenses for the second quarter of 2020 were $5.0 million compared to $24.4 million for the same period in 2019. The decrease was primarily due to reduced clinical trial expenses associated with the completion of the Company's Phase 3 clinical trials initiated in the third quarter of 2018.

General and administrative (G&A) expenses for the second quarter of 2020 were $3.2 million compared to $2.9 million in the same period in 2019. The increase was primarily due to an increase in share-based compensation for employees in our general and administrative and commercial functions partially offset by a decrease in headcount and related costs.

Interest expense, net in the second quarter of 2020 was $4.1 million compared to $0.1 million in the same period in 2019, primarily due to non-cash interest expense and amortization of debt discounts and deferred financing costs relating to the January 2020 private placement.

For the second quarter of 2020, the Company reported a net loss of $12.5 million compared to a net loss of $27.6 million for the same period in 2019.

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 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 the expected timing, terms and completion of the planned rights offering and the Company's plans, strategies and prospects for its business,

including with respect to the Company's scheduled meeting with the FDA. 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 the Company'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 the Company's 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 the Company's expectations regarding how far into the future the Company's cash on hand will fund the Company's ongoing operations, the sufficiency of the Company's cash resources and the Company's 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, the price of the Company's securities, the expected use of proceeds from the planned rights offering 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 the Company's beliefs and assumptions only as of the date of this press release. Except as required by law, the Company 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 June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Revenue	$ —	$ —	$ —	$ 37
Operating expenses:				
Research and development	(5,043)	(24,439)	(14,786)	(41,826)
General and administrative	(3,210)	(2,939)	(6,361)	(6,055)
Total operating expenses	(8,253)	(27,378)	(21,147)	(47,881)
Operating loss	(8,253)	(27,378)	(21,147)	(47,844)
Interest expense, net	(4,075)	(135)	(6,671)	(239)
Private placement transaction costs	—	—	(2,130)	—
Adjustments to fair value of derivatives	(12)	—	1,667	—
Other (expense) / income, net	(3)	32	(41)	156
Income tax expense	(178)	(157)	(299)	(291)
Net loss attributable to ordinary shareholders	$ (12,521)	$ (27,638)	$ (28,621)	$ (48,218)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.80)	$ (1.93)	$ (1.87)	$ (3.37)
Weighted average ordinary shares outstanding – basic and diluted	15,614,767	14,340,231	15,295,141	14,316,497
Net loss - GAAP	$ (12,521)	$ (27,638)	$ (28,621)	$ (48,218)
Interest expense - accrued interest and amortization on Exchangeable Notes and Royalty-Linked Notes	3,704		5,970	
Private placement transaction costs - not capitalized	-	—	2,130	—
Adjustments to fair value of derivatives	12	—	(1,667)	—
Non-GAAP adjusted loss	$ (8,805)	$ (27,638)	$ (22,188)	$ (48,218)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.80)	$ (1.93)	$ (1.87)	$ (3.37)
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.56)	$ (1.93)	$ (1.45)	$ (3.37)

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

	As of June 30, 2020	As of December 31, 2019
Cash and cash equivalents	$ 12,250	$ 4,801
Other assets	19,437	20,950
Total assets	**$ 31,687**	**$ 25,751**
Long-term debt, less current portion	$ 20,931	$ 7,625
Royalty-linked notes, less current portion	11,826	—
Derivative liability	25,371	—
Other liabilities	22,348	44,364
Total liabilities	80,476	51,989
Total shareholders' deficit	(48,789)	(26,238)
Total liabilities and shareholders' deficit	**$ 31,687**	**$ 25,751**