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): November 16, 2020

Iterum Therapeutics plc		
(Exact name of registrant as specified in its charter)		
Ireland	**001-38503**	**98-1283**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Ide

Block 2 Floor 3, Harcourt Centre,	
Harcourt Street,	
Dublin 2, Ireland	**n/a**
(Address of principal executive offices)	(Zip Co

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 2.02. Results of Operations and Financial Condition.

On November 16, 2020 Iterum Therapeutics plc (Iterum Therapeutics) issued a press release announcing its financial results for the third quarter ended September 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 Therapeutics, 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 nine months ended September 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 ($0.859 million); the non-cash amortization of the ENs and Royalty-Linked Notes ($3.0 million); one-time, non-capitalized financing transaction costs ($0.685 million) and the non-cash adjustments to the fair value of derivatives ($0.644 million) for the three months ended September 30, 2020, and the interest expense associated with accrued interest on the ENs payable in cash, shares or a combination of both upon exchange, redemption or at January 31, 2025 (the maturity date), whichever is earlier ($2.338 million); the non-cash amortization of the ENs and Royalty-Linked Notes ($7.491 million); one-time, non-capitalized financing transaction costs ($2.815 million); and the offsetting non-cash adjustments to the fair value of derivatives ($1.023 million) for the nine months ended September 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 financing transaction costs and the non-cash adjustments to the fair value of derivatives for the three and nine months ended September 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 November 16, 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: November 16, 2020

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

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

Iterum Therapeutics Reports Third Quarter 2020 Financial Results

--NDA Filing Expected Q4 2020--

DUBLIN, Ireland and CHICAGO, November 16, 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 third quarter ended September 30, 2020.

"Following the positive feedback we received from the FDA at our pre-NDA meeting in September, we have been diligently preparing our new drug application (NDA) for oral sulopenem for the treatment of uncomplicated urinary tract infections (uUTIs) due to quinolone-resistant pathogens for submission in the coming weeks, and are making preparations for a potential commercial launch of oral sulopenem in the U.S.," said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. "With potential approval anticipated within the next three quarters, we are pleased to be the first oral penem to market in the U.S., and the first approved product in uUTI in over 20 years, where quinolone-resistant pathogens now cause as many as one third of the 22 million uUTIs annually."

Q3 2020 Highlights and Recent Events

- **Positive meeting with the FDA resulting in continued preparation for submission of the NDA filing in the near-term:** Based on discussions with the FDA at a pre-NDA meeting in September 2020 and previous correspondence with the FDA, the Company plans to proceed with an NDA submission for oral sulopenem (sulopenem etzadroxil/probenecid) for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen in the fourth quarter of 2020. In June 2020, as previously disclosed, the Company announced topline data from the SURE-1 clinical trial demonstrating that oral sulopenem was statistically superior to ciprofloxacin in the treatment of patients with uUTI caused by a quinolone non-susceptible pathogen.
- **Extended cash runway:** In October 2020, the Company raised approximately $17.4 million gross proceeds (approximately $15.3 million net proceeds) in a registered public offering of ordinary shares, pre-funded warrants exercisable for ordinary shares and warrants exercisable for ordinary shares, which extended the Company's expected cash runway into the third quarter of 2021.
- **Presented results from two Phase 3 studies at the Infectious Disease Society of America (IDSA) IDWeek™ 2020 (IDWeek)**: In October 2020, the Company presented results from two of its Phase 3 clinical trials at IDWeek. The two data presentations included a poster presentation of the results of the SURE-2 clinical trial in complicated urinary tract

infections, and an oral abstract presentation of the results from the SURE-1 clinical trial in uUTIs.

Third Quarter 2020 Financial Results

As of September 30, 2020, the Company had cash and cash equivalents of $8.6 million and approximately 21.2 million shares outstanding. In October 2020, the Company issued and sold, in a public offering, ordinary shares, pre-funded warrants exercisable for ordinary shares and warrants exercisable for ordinary shares for aggregate gross proceeds of approximately $17.4 million and net proceeds of approximately $15.3 million after deducting fees payable to the placement agent and other estimated offering expenses. The Company expects that its current cash and cash equivalents, including the proceeds from the October 2020 financing, will be sufficient to fund its operations into the third quarter of 2021. 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 third quarter of 2020 were $3.9 million compared to $28.1 million for the same period in 2019. The decrease was primarily due to reduced clinical trial expenses and headcount associated with the completion of the Company's Phase 3 clinical trials, which had been initiated in the third quarter of 2018.

General and administrative (G&A) expenses for the third quarter of 2020 were $2.4 million compared to $2.9 million in the same period in 2019. The decrease was primarily due to a decrease in headcount and related costs, lower spending on pre-commercialization activities and reduced share-based compensation to directors, partially offset by an increase in share-based compensation for employees in our general and administrative functions.

Interest expense, net in the third quarter of 2020 was $4.2 million compared to $0.2 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 Company's Exchangeable Notes and Royalty-Linked Notes issued in 2020.

For the third quarter of 2020, the Company reported a net loss of $12.2 million compared to a net loss of $31.3 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 formulation 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 Company's plans, strategies and prospects for its business, including with respect to the Company's planned filing and FDA review of an NDA for oral sulopenem and the sufficiency of the Company's cash resources. 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 timing or likelihood of regulatory filings and approvals, changes in public policy or legislation, commercialization plans and timelines, if oral 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 Company's ability to continue as a going concern, the impact of COVID-19 and related responsive measures thereto, the Company's ability to maintain its listing on the Nasdaq Stock Market, 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 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 Securities and Exchange Commission 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.

Investor Contact:
Judy Matthews
Chief Financial Officer
312-778-6073
IR@iterumtx.com

ITERUM THERAPEUTICS PLC
Condensed Consolidated Statement of Operations
(In thousands except share and per share data)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Revenue	$ —	$ —	$ —	$ 37
Operating expenses:				
Research and development	(3,937)	(28,066)	(18,723)	(69,892)
General and administrative	(2,398)	(2,933)	(8,759)	(8,988)
Total operating expenses	(6,335)	(30,999)	(27,482)	(78,880)
Operating loss	(6,335)	(30,999)	(27,482)	(78,843)
Interest expense, net	(4,183)	(216)	(10,854)	(455)
Financing transaction costs	(685)	—	(2,815)	—
Adjustments to fair value of derivatives	(644)	—	1,023	—
Other income, net	68	48	27	204
Income tax expense	(420)	(104)	(719)	(395)
Net loss attributable to ordinary shareholders	$ (12,199)	$ (31,271)	$ (40,820)	$ (79,489)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.60)	$ (2.15)	$ (2.39)	$ (5.52)
Weighted average ordinary shares outstanding – basic and diluted	20,392,357	14,571,278	17,078,326	14,412,755
Net loss - GAAP	$ (12,199)	$ (31,271)	$ (40,820)	$ (79,489)
Interest expense - accrued interest and amortization on Exchangeable Notes and Royalty-Linked Notes	3,859	—	9,829	—
Financing transaction costs - not capitalized	685	—	2,815	—
Adjustments to fair value of derivatives	644	—	(1,023)	—
Non-GAAP adjusted loss	$ (7,011)	$ (31,271)	$ (29,199)	$ (79,489)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.60)	$ (2.15)	$ (2.39)	$ (5.52)
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.34)	$ (2.15)	$ (1.71)	$ (5.52)

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

	As of September 30, 2020	As of December 31, 2019
Cash and cash equivalents	$ 8,570	$ 4,801
Other assets	17,700	20,950
Total assets	**$ 26,270**	**$ 25,751**
Long-term debt, less current portion	$ 21,653	$ 7,625
Royalty-linked notes, less current portion	12,492	—
Derivative liabilities	26,097	—
Other liabilities	21,931	44,364
Total liabilities	82,173	51,989
Total shareholders' deficit	(55,903)	(26,238)
Total liabilities and shareholders' deficit	**$ 26,270**	**$ 25,751**