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): March 12, 2021

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,	**Not Applicable**
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))

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 March 12, 2021, Iterum Therapeutics plc, or Iterum Therapeutics, issued a press release announcing its financial results for the fourth quarter and year ended December 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 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 twelve months ended December 31, 2020, the interest expense associated with accrued interest on the Exchangeable Notes, or ENs, payable in cash, shares or a combination of both upon exchange, redemption or at January 31, 2025, or the Maturity Date, whichever is earlier ($0.842 million); the non-cash amortization of the ENs and Royalty-Linked Notes ($3.035 million); one-time, non-capitalized financing transaction costs ($0.033 million) and the non-cash adjustments to the fair value of derivatives ($2.768 million) for the three months ended December 31, 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 the Maturity Date, whichever is earlier ($3.18 million); the non-cash amortization of the ENs and Royalty-Linked Notes ($10.526 million); one-time, non-capitalized financing transaction costs ($2.848 million) and the non-cash adjustments to the fair value of derivatives ($1.745 million) for the twelve months ended December 31, 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 ENs payable in cash, shares or a combination of both upon exchange, redemption or at 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 twelve months ended December 31, 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 March 12, 2021

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: March 12, 2021

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

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

Iterum Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results

--NDA for Oral Sulopenem has PDUFA date of July 25, 2021--

--Cash Runway into First Half of 2023—

--Company to host conference call today at 8:30amET--

DUBLIN, Ireland and CHICAGO, March 12, 2021 -- 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 fourth quarter and year ended December 31, 2020.

"Iterum has made excellent progress in the last few months and we look forward to continuing that momentum throughout 2021. In the fourth quarter of 2020, we submitted a New Drug Application (NDA) for oral sulopenem for the treatment of uncomplicated urinary tract infections (uUTI) in patients with a quinolone non-susceptible organism, which is currently under review by the U.S. Food and Drug Administration (FDA) with a July 25, 2021 Prescription Drug User Fee Act (PDUFA) goal date. We estimate that the market for this indication is approximately 6.5 million uUTIs caused by a quinolone non-susceptible organism annually in the U.S.," said Corey Fishman, Chief Executive Officer. "Our priorities for the rest of this year are: (1) holding a positive Advisory Committee meeting in June, (2) completion of FDA review of our NDA by the end of July, (3) initiating the commercial launch in the fourth quarter, if approved, and (4) working with the FDA to understand the requirements for potential expansion of our label in uUTI to include all patients, if approved, and to potentially add the complicated urinary tract infection (cUTI) indication. In anticipation of these key milestones, we have raised sufficient capital to support the execution of our strategy as currently planned."

Highlights and Recent Events

- **NDA accepted for priority review by FDA with PDUFA goal date of July 25, 2021:** In January 2021, the FDA accepted for review our NDA for uUTI in patients with a quinolone non-susceptible organism. The FDA has designated our application as a priority review and consequently assigned a PDUFA goal date for completion of the review of oral sulopenem of July 25, 2021. The FDA currently plans to hold an advisory committee meeting to discuss the NDA on June 2, 2021.
- **Extended cash runway into first half of 2023:** In February 2021, we received total net proceeds of $74.3 million from an underwritten public offering and a registered direct offering which, along with proceeds received from the exercise of certain warrants and

existing cash and cash equivalents, has extended our cash runway into the first half of 2023, based on our current operating plan. As of February 28, 2021, we had approximately 176.5 million ordinary shares outstanding.

- **Announced collaboration with a third-party provider of commercialization services:** In February 2021, we engaged EVERSANA™, a leading provider of commercial services to the life science industry, to initiate certain pre-launch activities. We are in the process of finalizing an agreement with EVERSANA™ to provide commercialization services to launch oral sulopenem, if approved.

Fourth Quarter and Full Year 2020 Financial Results

As of December 31, 2020 , Iterum had cash and cash equivalents of $14.5 million. In February 2021, Iterum received total net proceeds of $74.3 million from an underwritten public offering and a registered direct offering . Iterum expects that its current cash and cash equivalents, including the proceeds from these recent financings and proceeds received from the exercise of certain warrants, will be sufficient to fund its operations into the first half of 2023.

Research and development (R&D) expenses for the fourth quarter and full year 2020 were $2.4 million and $21.1 million, respectively, compared to $20.9 million and $90.8 million for the
same periods in 2019. The decreases for both the three-month and twelve-month periods were primarily due to the substantial completion of our three Phase 3 clinical trials in 2019.

General and administrative (G&A) expenses for the fourth quarter and full year 2020 were $2.3 million and $11.1 million, respectively, compared to $2.3 million and $11.3 million for the
same periods in 2019. The slight decrease for the full year was primarily due to lower consulting spend on pre-commercialization activities and lower headcount, partially offset by higher share-based compensation expense.

Interest expense, net for the fourth quarter and full year 2020 was $4.2 million and $15.1 million, respectively, compared to $0.4 million and $0.9 million for the same periods 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 fourth quarter and full year 2020, Iterum reported a net loss of $11.2 million and $52.0 million, respectively, compared to a net loss of $23.6 million and $103.1 million for the same periods in 2019.

Upcoming Investor Presentations

- *Corporate presentation at the Needham & Company 20th Annual Healthcare Virtual Conference from April 12-15, 2021*
- *Corporate presentation at the RBC Capital Markets Global Healthcare Virtual Conference from May 18-19, 2021*

Conference Call and Webcast Details

- Iterum will host a conference call and webcast today, Friday, March 12, 2021 at 8:30 a.m. Eastern Time. To register for this conference call, please use this link: https://www.incommglobalevents.com/registration/client/6960/iterum-therapeutics-4th-quarter-and-full-year-2020/. To access the webcast, click on this link: https://event.on24.com/wcc/r/3046063/2E404D4F9FF92585C41DAAAF17569C27. A recording will be available until Friday, March 19, 2021. To access the replay, please click on the following link and enter the access code 939536 https://www.incommglobalevents.com/replay/5511/iterum-therapeutics-4th-quarter-and-full-year-2020/

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. We believe that sulopenem and oral sulopenem have the potential to be important new treatment alternatives to address the growing concerns related to antibacterial resistance without the known toxicities of some of the most widely used antibiotics, specifically fluoroquinolones. Oral sulopenem is currently under FDA review for uncomplicated urinary tract infections in patients with a quinolone non-susceptible pathogen and has a PDUFA goal date of July 25, 2021.

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 the Company's plans, strategies and prospects for its business, including with respect to the timing of review by the FDA of the NDA for oral sulopenem and the Company's expectations for potential approval on the PDUFA date, the market potential for sulopenem, commercialization activities including the ability to enter into a definitive agreement with respect to commercialization services, the ability to expand any approved label for sulopenem, the ability to add the cUTI indication, and the sufficiency of the

Company's cash resources to execute its strategy. 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 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, strategic, financial and financing alternatives, including the terms, timing, structure, value, benefits and costs of any corporate, strategic, financial or financing alternative and the Company's ability to complete one at all and other factors discussed under the caption "Risk Factors" in its Annual Report on Form 10- K filed with the Securities and Exchange Commission (the "SEC") on March 12, 2021, 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
Consolidated Statement of Operations
(In thousands except share and per share data)
(Unaudited)

	Three months ended December 31,		Year ended December 31,	
	2020	**2019**	**2020**	**2019**
Revenue	$ —	$ —	$ —	$ 37
Operating expenses:				
Research and development	(2,351)	(20,882)	(21,074)	(90,774)
General and administrative	(2,293)	(2,296)	(11,052)	(11,284)
Total operating expenses	(4,644)	(23,178)	(32,126)	(102,058)
Operating loss	(4,644)	(23,178)	(32,126)	(102,021)
Interest expense, net	(4,243)	(406)	(15,097)	(861)
Financing transaction costs	(33)	—	(2,848)	
Adjustments to fair value of derivatives	(2,768)	—	(1,745)	—
Extinguishment of debt	340	—	340	—
Other income, net	186	(8)	213	196
Income tax expense	(24)	(49)	(743)	(444)
Net loss attributable to ordinary shareholders	$ (11,186)	$ (23,641)	$ (52,006)	$ (103,130)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.28)	$ (1.59)	$ (2.17)	$ (7.10)
Weighted average ordinary shares outstanding – basic and diluted	40,645,864	14,866,838	24,009,818	14,518,036
Net loss - GAAP	$ (11,186)	$ (23,641)	$ (52,006)	$ (103,130)
Interest expense - accrued interest and amortization on Exchangeable Notes and Royalty-Linked Notes	3,877	—	13,706	—
Financing transaction costs - not capitalized	33	—	2,848	—
Adjustments to fair value of derivatives	2,768	—	1,745	—
Non-GAAP adjusted loss	$ (4,508)	$ (23,641)	$ (33,707)	$ (103,130)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.28)	$ (1.59)	$ (2.17)	$ (7.10)
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.11)	$ (1.59)	$ (1.40)	$ (7.10)

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

	As of December 31, 2020	**As of December 31, 2019**
Cash and cash equivalents	$ 14,508	$ 4,801
Other assets	18,284	20,950
Total assets	**$ 32,792**	**$ 25,751**
Long-term debt, less current portion	$ 22,462	$ 7,625
Royalty-linked notes, less current portion	13,389	—
Derivative liabilities	28,865	—
Other liabilities	18,635	44,364
Total liabilities	83,351	51,989
Total shareholders' deficit	(50,559)	(26,238)
Total liabilities and shareholders' deficit	**$ 32,792**	**$ 25,751**