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, 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 March 12, 2020, Iterum Therapeutics plc ("Iterum Therapeutics") issued a press release announcing its financial results for the fourth quarter and year ended December 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 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 the related per share measure) to exclude from reported GAAP net loss (and the related per share measure) for the fourth quarter and year ended December 31, 2018 the $7.5 million clinical milestone payment made to Pfizer on first patient dosing with sulopenem IV and $15.0 million in clinical milestone payments made to Pfizer on first patient dosing with oral sulopenem ($7.5 million) and on first patient dosing with sulopenem IV ($7.5 million), respectively. 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 $7.5 million clinical milestone payment and $15.0 million in clinical milestone payments to Pfizer for the fourth quarter and year ended December 31, 2018, respectively. 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 March 12, 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: March 12, 2020

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

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

Iterum Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results

--Topline data from cUTI and uUTI pivotal trials on track to report around the end of Q1--

--NDAs anticipated to file with the FDA in mid-2020--

DUBLIN, Ireland and CHICAGO, March 12, 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 fourth quarter and year ended December 31, 2019.

"2019 was a year of incredible progress for Iterum. We completed enrollment in all three Phase 3 clinical trials of sulopenem and reported topline results from our complicated intra-abdominal infections (cIAI) trial," said Corey Fishman, Chief Executive Officer of Iterum Therapeutics plc. "2020 is a pivotal year for the company. We started the year by raising additional capital to fund the company through topline results of the remaining two Phase 3 studies, complicated urinary tract infections (cUTI) and uncomplicated urinary tract infections (uUTI), planned submission of two new drug applications (NDAs) to the U.S. Food and Drug Administration (FDA) and preparations for a potential commercial launch in 2021."

2019 Highlights and Recent Events

- **Completed enrollment in all Phase 3 pivotal clinical trials:** In the fourth quarter of 2019, Iterum completed patient enrollment in its two remaining clinical trials, **Su**lopenem for **R**esistant **E**nterobacteriaceae (SURE) 1 in uUTI and SURE 2 in cUTI. Overall, more than 3,700 patients were enrolled in our Phase 3 clinical trials of sulopenem since initiation in the third quarter of 2018.
- **Announced topline results in first Phase 3 trial:** In December 2019, Iterum announced that it narrowly missed the primary endpoint of its SURE 3 clinical trial cIAI. While the trial narrowly missed the primary endpoint, we believe the secondary supporting analysis and safety data support the potential for sulopenem in the treatment of multi-drug resistant infections.
- **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.

- **Filed two non-provisional patent applications with United States Patent and Trademark Office:** One patent application addressed the effect of probenecid on the plasma concentrations of sulopenem after multi-day dosing and the second patent application

related to a method of preparing a bilayer tablet composed of sulopenem etzadroxil and probenecid which resulted in an increase in the amount of sulopenem in the blood relative to dosing each agent in a separate formulation. If either patent is granted, it would provide 20 years of intellectual property protection for oral sulopenem from the date the non-provisional patent application was filed (to 2039). The current U.S. composition of matter patent on sulopenem etzadroxil expires in 2029 with potential extension to 2034 under the Hatch-Waxman Act.

Fourth Quarter and Full Year 2019 Financial Results

As of December 31, 2019 , Iterum had cash and cash equivalents of $4.8 million and approximately 14.5 million shares outstanding. In January 2020, Iterum received net proceeds of $46.7 million from the private placement with accredited investors of 6.500% exchangeable senior subordinated notes due 2025 and limited recourse royalty-linked senior subordinated notes . Iterum expects that its current cash and cash equivalents, including the proceeds from this recent financing, will be sufficient to fund its operations into the second half of 2020.

Research and development (R&D) expenses for the fourth quarter and full year 2019 were $20.9 million and $90.8 million, respectively, compared to $21.5 million and $68.6 million for the
same periods in 2018. The increases for both the three-month and twelve-month periods were primarily due to higher clinical trial expenses associated with the three Phase 3 clinical trials initiated in the third quarter of 2018, partially offset by milestone payments made to Pfizer Inc. of $7.5 million in the fourth quarter of 2018 and $15.0 million in the 2018 twelve-month period.

General and administrative (G&A) expenses for the fourth quarter and full year 2019 were $2.3 million and $11.3 million, respectively, compared to $2.7 million and $8.8 million for the
same periods in 2018. The increase for the full year was primarily due to increased costs associated with operating as a public company and additional headcount to support business activities.

For the fourth quarter and full year 2019, Iterum reported a net loss of $23.6 million and $103.1 million, respectively, compared to a net loss of $24.3 million and $77.1 million for the same periods in 2018.

Upcoming Scientific and Investor Presentations

- Corporate presentation at the Needham & Company 19th Annual Healthcare Conference from April 14-15, 2020 in New York City, New York
- A scientific presentation at the 30th European Congress of Clinical Microbiology and Infectious Diseases from April 18-21, 2020 in Paris, France
- Corporate presentation at the RBC Capital Markets Global Healthcare Conference from May 19-20, 2020 in New York City, New York
- Multiple scientific presentations at American Society of Microbiology (ASM) Microbe 2020 from June 18-22, 2020 in Chicago, IL

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, and other factors discussed under the caption “Risk Factors” in our Annual Report on Form 10- K filed with the Securities and Exchange Commission (the “SEC”) on March 12, 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:
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 December 31,		Year ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenue	$ -	$ 239	$ 37	$ 869
Operating expenses:				
Research and development	(20,882)	(21,460)	(90,774)	(68,647)
General and administrative	(2,296)	(2,723)	(11,284)	(8,781)
Total operating expenses	(23,178)	(24,183)	(102,058)	(77,428)
Operating loss	(23,178)	(23,944)	(102,021)	(76,559)
Interest (expense) / income, net	(406)	(297)	(861)	(426)
Other (expense) / income, net	(8)	189	196	401
Income tax expense	(49)	(206)	(444)	(472)
Net loss attributable to ordinary shareholders	$ (23,641)	$ (24,258)	$ (103,130)	$ (77,056)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (1.59)	$ (1.72)	$ (7.10)	$ (8.82)
Weighted average ordinary shares outstanding – basic and diluted	14,866,838	14,108,604	14,518,036	8,734,109
Net loss - GAAP	(23,641)	(24,258)	(103,130)	(77,056)
Milestone payments to Pfizer	-	7,500	-	15,000
Non-GAAP adjusted loss	$ (23,641)	$ (16,758)	$ (103,130)	$ (62,056)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (1.59)	$ (1.72)	$ (7.10)	$ (8.82)
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	$ (1.59)	$ (1.19)	$ (7.10)	$ (7.11)

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

	As of December 31, 2019	As of December 31, 2018
Cash, cash equivalents and short-term investments	$ 4,801	$ 84,551
Other assets	20,950	13,320
Total assets	**$ 25,751**	**$ 97,871**
Long-term debt, less current portion	7,625	13,079
Other liabilities	44,364	13,170
Total liabilities	51,989	26,249
Total shareholders' (deficit) / equity	(26,238)	71,622
Total liabilities and shareholders' (deficit) / equity	**$ 25,751**	**$ 97,871**