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 25, 2019

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:

☐ 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).

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 25, 2019, Iterum Therapeutics plc ("Iterum") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2018. 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's financial results presented in accordance with U.S. generally accepted accounting principles, or GAAP, Iterum 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) the $15.0 million in clinical milestone payments made to Pfizer on first patient dosed with oral sulopenem in a Phase 3 trial ($7.5 million) and on first patient dosed with sulopenem IV in a Phase 3 trial ($7.5 million). Iterum 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's management in assessing Iterum's performance and results from period to period. This non-GAAP measure closely aligns with the way management measures and evaluates Iterum's 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 $15.0 million in clinical milestone payments to Pfizer. Because of the non-standardized definitions of non-GAAP financial measures, Non-GAAP adjusted net loss used by Iterum 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 25, 2019

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 25, 2019

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

FOR IMMEDIATE RELEASE

Iterum Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results

—On Track to Complete its Three Phase 3 Clinical Trials in 2019—

—Received Qualified Infectious Disease Product Designation in Four Additional Indications—

—Fast Track Designation received from the FDA in seven potential indications—

DUBLIN, Ireland and CHICAGO, March 25, 2019 — Iterum Therapeutics plc (Nasdaq: ITRM), a clinical-stage pharmaceutical company developing anti-infectives against multi-drug resistant pathogens, today reported financial results for the fourth quarter and year ended December 31, 2018.

"We made tremendous progress in 2018. We raised over $80 million in an IPO to fund three Phase 3 trials in three indications of our lead asset, sulopenem, which were initiated in the third quarter," said Corey Fishman, Chief Executive Officer of Iterum Therapeutics plc. "In 2019, we remain focused on completing all three trials, delivering top-line results, and preparing our New Drug Applications for submission to the U.S. Food and Drug Administration (FDA)."

2018 Highlights and Recent Events

- **Initiated three Phase 3 pivotal clinical trials:** In the third quarter of 2018, Iterum initiated three Phase 3 clinical trials in each of the following indications: uncomplicated urinary tract infections (uUTI), complicated urinary tract infections (cUTI), and complicated intra-abdominal infections (cIAI). Data from these trials are expected in the second half of 2019.
- **Strengthened the balance sheet:** In May 2018, Iterum raised approximately $80 million of gross proceeds in an initial public offering of ordinary shares. In April 2018, Iterum completed a debt financing with Silicon Valley Bank for up to $30 million, $15 million of which was funded upfront. In February 2018, Iterum closed its Series B-2 financing raising over $32 million.
- **Received QIDP and Fast Track designation from the FDA:** Oral sulopenem and sulopenem IV received QIDP designation in four new indications, community-acquired bacterial pneumonia, acute bacterial prostatitis, gonococcal urethritis, and pelvic inflammatory disease. These indications, as well as the three indications currently in Phase 3 development, have also received Fast Track designation from the FDA.
- **Presented data at scientific congresses:** Iterum presented important data at the American Society of Microbiology MICROBE meeting and during IDWeek that underscores the need for new antibiotics, particularly oral therapies like sulopenem, which can be used in both the community and hospital settings.

Fourth Quarter and Full-Year 2018 Financial Results

As of December 31, 2018, Iterum had cash, cash equivalents and short-term investments of $84.6 million and approximately 14.4 million shares outstanding. Iterum expects that its cash, cash equivalents and short-term investments, along with its available borrowings, will be sufficient to fund operations into the first quarter of 2020.

Research and development (R&D) expenses for the fourth quarter and full year 2018 were $21.5 million and $68.6 million, respectively, compared to $8.2 million and $25.5 million for the same periods in 2017. 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, as well as clinical milestone payments to Pfizer of $7.5 million and $15.0 million in the fourth quarter and full year, respectively.

General and administrative (G&A) expenses for the fourth quarter and full year 2018 were $2.7 million and $8.8 million, respectively, compared to $1.3 million and $4.5 million for the same periods in 2017. The increase was primarily due to increased costs associated with operating as a public company, additional headcount to support business activities, and increased marketing and market research expenses.

For the fourth quarter and full year 2018, Iterum reported a net loss of $24.3 million and $77.1 million, respectively, compared to a net loss of $9.1 million and $29.4 million for the same periods in 2017.

Upcoming Scientific and Investor Presentations

- Corporate presentation at the Needham & Company 18th Annual Healthcare Conference on Tuesday, April 9, 2019 at 1:30 p.m. in New York, New York
- Multiple scientific presentations at the 29th European Congress of Clinical Microbiology and Infectious Diseases from April 13-16, 2019 in Amsterdam, Netherlands
- Corporate presentation at the RBC Capital Markets Global Healthcare Conference from May 21-22, 2019 in New York, New York
- Multiple scientific presentations at American Society of Microbiology (ASM) Microbe 2019 from June 20-24, 2019 in San Francisco, California

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 effective treatment of resistant pathogens in the community, make possible the avoidance of hospitalization, and 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 three pivotal Phase 3 clinical trials for uncomplicated urinary tract infections, complicated urinary tract infections, and complicated intra-abdominal infections.

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 regarding future revenue, expenses, cash flows and net income or loss, the sufficiency of cash resources, the development, therapeutic and market potential of sulopenem, the timing, progress and results of clinical trials, and the expected timing of NDA filings. 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 Iterum Therapeutics’ 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 Iterum Therapeutics’ control, including the uncertainties inherent in the initiation and conduct of clinical trials, clinical trial patient enrollment, availability and timing of data from clinical trials, changes in regulatory requirements or decisions of regulatory authorities, commercialization plans and timelines, if approved, the actions of third-party clinical research organizations, suppliers and manufacturers 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 25, 2019, and other documents filed with the SEC from time to time. Forward-looking statements represent Iterum Therapeutics’ beliefs and assumptions only as of the date of this press release. Except as required by law, Iterum Therapeutics 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenue	$ 239	$ 349	$ 869	$ 508
Operating expenses:				
Research and development	(21,460)	(8,241)	(68,647)	(25,499)
General and administrative	(2,723)	(1,312)	(8,781)	(4,464)
Total operating expenses	(24,183)	(9,553)	(77,428)	(29,963)
Operating loss	(23,944)	(9,204)	(76,559)	(29,455)
Interest (expense) / income, net	(297)	108	(426)	277
Other income, net	189	29	401	216
Income tax expense	(206)	(51)	(472)	(444)
Net loss attributable to ordinary shareholders	$ (24,258)	$ (9,118)	$ (77,056)	$ (29,406)
Net loss per share attributable to ordinary shareholders — basic and diluted	$ (1.72)	$ (43.24)	$ (8.82)	$ (170.84)
Weighted average ordinary shares outstanding — basic and diluted	14,108,604	210,859	8,734,109	172,130
Net Loss — GAAP	(24,258)	(9,118)	(77,056)	(29,406)
Milestone Payments to Pfizer	7,500	—	15,000	—
Non-GAAP adjusted loss	(16,758)	(9,118)	(62,056)	(29,406)
Net loss per share attributable to ordinary shareholders — basic and diluted	$ (1.72)	$ (43.24)	$ (8.82)	$ (170.84)
Non-GAAP net loss per share attributable to ordinary shareholders — basic and diluted	$ (1.19)	$ (43.24)	$ (7.11)	$ (170.84)

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

	Year Ended December 31,	
	2018	2017
Cash, cash equivalents, restricted cash andshort-term investments	$ 84,671	$ 39,216
Other assets	13,200	7,541
Total assets	**$ 97,871**	**$ 46,757**
Long-term debt, less current portion	13,079	—
Other liabilities	13,170	7,206
Total liabilities	$ 26,249	$ 7,206
Total convertible preferred shares and shareholders' equity	71,622	39,551
Total liabilities, convertible preferred shares and shareholders' equity	**$ 97,871**	**$ 46,757**