
**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 14, 2018

Iterum Therapeutics plc

(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction
of incorporation)

001-38503
(Commission File Number)

98-1283148
(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 August 14, 2018, Iterum Therapeutics plc (“Iterum”) issued a press release announcing certain financial results for its second quarter ended June 30, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release of Iterum Therapeutics plc, dated August 14, 2018</u>

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 14, 2018

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

**FOR IMMEDIATE RELEASE****Iterum Reports Second Quarter 2018 Financial Results and Recent Highlights**

DUBLIN and CHICAGO, August 14, 2018 — Iterum Therapeutics plc (Nasdaq: ITRM), a clinical-stage pharmaceutical company developing anti-infectives against multi-drug resistant pathogens, today reported financial results for the quarter ended June 30, 2018.

“Iterum made significant progress in the second quarter of 2018 with the completion of our IPO, which will allow us to fund our planned Phase 3 clinical trials and regulatory submissions for sulopenem in three indications,” said Corey Fishman, Chief Executive Officer of Iterum Therapeutics plc. “The first trial is underway for the treatment of women with uncomplicated urinary tract infections, a very large and underserved market. We also plan to initiate two additional Phase 3 trials for sulopenem in the next few months in complicated urinary tract infections and complicated intra-abdominal infections. We expect top-line data from all three trials during the second half of 2019, followed by our NDA submissions by the end of 2019.”

Second Quarter and Recent Highlights

- **Completed initial public offering:** In May 2018, Iterum closed its initial public offering of ordinary shares at a public offering price of \$13.00 per share. Including shares purchased by the underwriters pursuant to their option exercise, Iterum received net proceeds of approximately \$74.2 million, net of underwriting discounts and commissions and offering expenses, from the offering of an aggregate of 6,350,000 shares.
- **Initiated a Phase 3 clinical trial of oral sulopenem in uncomplicated urinary tract infections:** In August 2018, the company initiated Sulopenem for Resistant Enterobacteriaceae (SURE) 1 trial of oral sulopenem in uncomplicated urinary tract infections (uUTI). The SURE 1 trial is a randomized, multi-center, double-blind study to measure efficacy, tolerability, and safety of oral sulopenem vs. oral ciprofloxacin for the treatment of uUTI in adult women. Oral sulopenem, if approved, could be the first antibiotic approved for uUTI in over 20 years.
- **Presented data at ASM Microbe:** In June 2018, Iterum presented data on the prevalence of resistant infections and *in vitro* activity of sulopenem at the American Society of Microbiology (ASM) MICROBE meeting in Atlanta.

Second Quarter 2018 Financial Results

As of June 30, 2018, Iterum had cash, cash equivalents and short-term investments of \$135.3 million and approximately 14.2 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 through the fourth quarter of 2019.

For the full year 2018, operating expenses are expected to be approximately \$90-95 million, which includes the milestone payments owed to Pfizer on first patient dosed in a Phase 3 trial with oral and IV sulopenem of \$7.5 million for each product (or \$15 million total).

Research and development expenses for the second quarter of 2018 were \$13.7 million compared to \$5.3 million for the same period in 2017. The \$8.4 million increase was primarily due to the increase in clinical trial expenses and clinical trial materials as Iterum prepared for the initiation of its three Phase 3 clinical trials in the second half of 2018.

General and administrative expenses for the second quarter of 2018 were \$1.9 million compared to \$1.1 million for the same period in 2017. This increase was primarily due to increased headcount to support research and development efforts, increased costs associated with operating as a public company and pre-commercialization activities.

Iterum reported a net loss for the second quarter of 2018 of \$15.7 million compared to a net loss of \$6.3 million for the same period in 2017.

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 with oral and IV formulations that 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 QIDP designations for its oral and IV formulations for the treatment of uUTI, complicated urinary tract infection and complicated intra-abdominal infection. 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 financial guidance for 2018, expectations regarding future revenue, expenses, cash flows and net income or loss, 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on or about August 14, 2018, 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.

Contact:

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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,	
	2018	2017	2018	2017
Revenue	\$ 185	\$ —	\$ 376	\$ —
Operating expenses:				
Research and development	(13,725)	(5,290)	(24,604)	(9,824)
General and administrative	(1,886)	(1,123)	(3,401)	(2,131)
Total operating expenses	(15,611)	(6,413)	(28,005)	(11,955)
Operating loss	(15,426)	(6,413)	(27,629)	(11,955)
Interest income / (expense), net	(76)	46	9	46
Other income / (expense), net	(177)	165	(116)	97
Income tax expense	(68)	(78)	(157)	(305)
Net loss attributable to ordinary shareholders	\$ (15,747)	\$ (6,280)	\$ (27,893)	\$ (12,117)
Net loss per share attributable to ordinary shareholders — basic and diluted	\$ (2.22)	\$ (39.44)	\$ (6.72)	\$ (82.82)
Weighted average ordinary shares outstanding — basic and diluted	7,085,655	159,221	4,148,535	146,311

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

	As of June 30, 2018	As of December 31, 2017
Cash, cash equivalents and short-term investments	\$ 135,271	\$ 39,216
Other assets	10,199	7,541
Total assets	\$ 145,470	\$ 46,757
Long-term debt	14,505	—
Other liabilities	12,435	7,206
Total liabilities	\$ 26,940	\$ 7,206
Total convertible preferred shares and shareholders' equity	118,530	39,551
Total liabilities, convertible preferred shares and shareholders' equity	\$ 145,470	\$ 46,757