# 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 14, 2018**

# 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 November 14, 2018, Iterum Therapeutics plc ("Iterum") issued a press release announcing certain financial results for its third quarter ended September 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.

***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 $7.5 million milestone payment made to Pfizer on first patient dosing in the SURE 1 clinical trial with oral sulopenem. 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 $7.5 million milestone payment 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 reconcilliation 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 November 14, 2018 |

**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 14, 2018

By: /s/ Judith M. Matthews
Judith M. Matthews
Chief Financial Officer

**Exhibit 99.1**

**FOR IMMEDIATE RELEASE**

## Iterum Reports Third Quarter 2018 Financial Results and Recent Highlights

**DUBLIN, Ireland and CHICAGO, Nov. 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 September 30, 2018.

"The third quarter was highlighted by the initiation of our entire Phase 3 program for sulopenem. With all three clinical trials underway, we reiterate our goal of delivering top-line data in the second half of 2019," said Corey Fishman, Chief Executive Officer of Iterum Therapeutics plc. "Iterum is now that much closer to bringing this important oral therapy to market, allowing effective treatment in the community when a multi-drug resistant infection in one of our three indications is suspected or confirmed."

### Third Quarter and Recent Highlights

- **Initiated all three planned Phase 3 pivotal clinical trials for sulopenem, which includes**: 1) a Phase 3 uncomplicated urinary tract infections (uUTI) clinical trial, known as SUlopenem for Resistant Enterobacteriaceae (SURE) 1, comparing oral sulopenem to oral ciprofloxacin in women with uUTI; 2) a Phase 3 complicated urinary tract infections (cUTI) clinical trial, known as SURE 2, comparing IV sulopenem followed by oral sulopenem to IV ertapenem followed by oral ciprofloxacin in adults with cUTI; and 3) a Phase 3 complicated intra-abdominal infections (cIAI) clinical trial know as SURE 3, comparing IV sulopenem followed by oral sulopenem to IV ertapenem followed by a combination of oral ciprofloxacin and oral metronidazole in adults with cIAI.
- **Presented data at IDWeek**: In October 2018, Iterum presented three posters including data on the pharmacokinetics of sulopenem, the *in vitro* antibacterial activity of sulopenem and the prevalence of enterobacteriaceae resistant to all major classes of oral antibiotics from outpatient urine cultures in the United States and the effect on clinical outcomes at the Infectious Diseases Society of America (IDSA) meeting in San Francisco.

### Third Quarter 2018 Financial Results

As of September 30, 2018, Iterum had cash, cash equivalents and short-term investments of $108.1 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 $85-90 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 (R&D) expenses for the third quarter of 2018 were $22.6 million compared to $7.4 million for the same period in 2017. One of the two $7.5 million milestone payments owed to Pfizer as described above was recorded and paid in the third quarter. The remaining $7.5 million milestone is expected to be recorded and paid in the fourth quarter of 2018. Excluding the Pfizer milestone payment, the $7.7 million increase in R&D expenses was primarily due to the increase in clinical trial expenses associated with the three Phase 3 clinical trials initiated in the third quarter of 2018.

General and administrative expenses for the third quarter of 2018 were $2.7 million compared to $1.0 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 third quarter of 2018 of $24.9 million compared to a net loss of $8.2 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 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 has received QIDP designations for its oral and IV formulations for the treatment of uncomplicated urinary tract infection, 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’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 Iterum’s 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 November 14, 2018, and other documents filed with the SEC from time to time. Forward-looking statements represent Iterum’s beliefs and assumptions only as of the date of this press release. Except as required by law, Iterum 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:**

Contact:
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Chief Executive Officer
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**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, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Revenue | $ 254 | $ 159 | $ 630 | $ 159 |
| Operating expenses: | | | | |
| Research and development | (22,583) | (7,434) | (47,188) | (17,258) |
| General and administrative | (2,657) | (1,021) | (6,058) | (3,152) |
| Total operating expenses | (25,240) | (8,455) | (53,246) | (20,410) |
| Operating loss | (24,986) | (8,296) | (52,616) | (20,251) |
| Interest income / (expense), net | (138) | 123 | (100) | 169 |
| Other income / (expense), net | 328 | 90 | 183 | 187 |
| Income tax expense | (109) | (88) | (266) | (393) |
| Net loss attributable to ordinary shareholders | $ (24,905) | $ (8,171) | $ (52,799) | $ (20,288) |
| Net loss per share attributable to ordinary shareholders—basic and diluted | $ (1.77) | $ (44.16) | $ (7.42) | $ (127.42) |
| Weighted average ordinary shares outstanding—basic and diluted | 14,034,631 | 185,040 | 7,115,655 | 159,221 |
| Net Loss—GAAP | (24,905) | (8,171) | (52,799) | (20,288) |
| Milestone Payment to Pfizer | 7,500 | — | 7,500 | — |
| Non-GAAP adjusted loss | (17,405) | (8,171) | (45,299) | (20,288) |
| Net loss per share attributable to ordinary shareholders—basic and diluted | $ (1.77) | $ (44.16) | $ (7.42) | $ (127.42) |
| Non-GAAP net loss per share attributable to ordinary shareholders—basic and diluted | $ (1.24) | $ (44.16) | $ (6.37) | $ (127.42) |

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

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 108,107 | $ 39,216 |
| Other assets | 8,758 | 7,541 |
| **Total assets** | **$ 116,865** | **$ 46,757** |
| Long-term debt | 14,541 | — |
| Other liabilities | 8,226 | 7,206 |
| Total liabilities | $ 22,767 | $ 7,206 |
| Total convertible preferred shares and shareholders' equity | 94,098 | 39,551 |
| **Total liabilities, convertible preferred shares and shareholders' equity** | **$ 116,865** | **$ 46,757** |