

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): April 08, 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:

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
Ordinary Shares, par value \$0.01 per share	ITRM	Nasdaq Capital Market

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 8.01. Other Events.

On April 8, 2021, Iterum Therapeutics plc (the “Company”) received notice from the U.S. Food and Drug Administration (“FDA”) that it needs more time to review materials that have been provided by the Company in support of the Company’s new drug application (“NDA”) for sulopenem etzadroxil/probenecid for the treatment of uncomplicated urinary tract infections in patients with a quinolone non-susceptible pathogen and therefore, the previously scheduled FDA Antimicrobial Drugs Advisory Committee (the “Panel”) on June 2, 2021 has been postponed. A new date for the Panel review of the Company’s NDA has not yet been confirmed and the Company continues to work closely with the FDA to facilitate its review.

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: April 09, 2021

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