

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): July 29, 2025

Iterum Therapeutics plc

(Exact name of Registrant as Specified in Its Charter)

Ireland
(State or Other Jurisdiction
of Incorporation)

001-38503
(Commission File Number)

Not applicable
(IRS Employer
Identification No.)

25 North Wall Quay
Dublin 1, Ireland
(Address of Principal Executive Offices)

Not applicable
(Zip Code)

Registrant's Telephone Number, Including Area Code: +353 1 6694820

(Former Name or Former Address, if Changed Since Last Report)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	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 1.01 Entry into a Material Definitive Agreement.

On July 29, 2025, Iterum Therapeutics International Limited (“Iterum Ireland”), a subsidiary of Iterum Therapeutics plc (the “Company”), entered into a Commercial Manufacturing and Supply Agreement (the “Agreement”) with ACS Dobfar S.p.A, together with its affiliates (“ACS”) for the manufacture and supply of the Company’s approved product, being the ORLYNVAH™ bilayer tablets, for commercial supply purposes. Pursuant to the Agreement, ACS will manufacture, supply and deliver such quantities of the ORLYNVAH™ bilayer tablets and/or sulopenem etzadroxil bulk drug substance, in each case, as required by Iterum Ireland (collectively, the “Products”).

Under the terms of the Agreement, ACS will be responsible for the procurement and qualification of the materials and components to manufacture the Products, subject to receiving instructions from Iterum Ireland regarding orders to be placed with third-party manufacturers of such materials and components including the appropriate quantities and pricing, and shall manufacture the Products in accordance with the specifications, manufacturing process and applicable laws further described in the Agreement. The Agreement has an initial term of five years from the effective date of the Agreement, followed by a two-year automatic renewal period, absent termination by either party in accordance with the terms of the Agreement. The Agreement provides for pricing for the Products based on a per kilogram or per bottle of tablets basis, depending on the type of Product to be manufactured, and subject to any potential cost reduction adjustments. Pursuant to the Agreement, Iterum Ireland will provide ACS with a rolling forecast for its orders of the Products for commercial use, a certain portion of which will be binding and considered firm orders, and ACS shall manufacture, supply and deliver such firm orders. ACS shall also use commercially reasonable efforts to manufacture and deliver by the specified delivery dates in the applicable purchase order any amounts of Products ordered by Iterum Ireland that are greater than the amounts of the forecast plus upside.

The Agreement includes customary mutual obligations on the parties to protect and not disclose the confidential information and intellectual property of the other, insurance, indemnification and limitation of liability provisions customary for manufacturing and supply contracts of this type. The Agreement also includes acceptance, warranty, quality, testing and inspection, and audit terms and conditions, as well as provisions relating to compliance by ACS with current Good Manufacturing Practices.

The foregoing description of the Agreement is qualified in its entirety by reference to the full text of the Agreement, a copy of which the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ended September 30, 2025.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Iterum Therapeutics plc

Date: August 4, 2025

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