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 3, 2026

Roivant Sciences Ltd.

(Exact name of registrant as specified in its charter)

Bermuda	**001-40782**	**98-1173944**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

7th Floor
50 Broadway
London SW1H 0DB
United Kingdom

1 Pennsylvania Plaza
Floor 54
New York, NY 10119
United States[1]

Viaduktstrasse 8
4051 Basel
Switzerland[1]
(Address of principal executive offices, and Zip Code)

+44 207 400-3347
Registrant's Telephone Number, Including Area Code

Not Applicable
(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 (*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:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Shares, $0.0000000341740141 per share	**ROIV**	**The Nasdaq Global Select 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. ☐

1 Addresses of wholly-owned subsidiaries of the Registrant.

Item 7.01. Regulation FD Disclosure

On March 3, 2026, Roivant Sciences Ltd. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has accepted the New Drug Application ("NDA") for brepocitinib for the treatment of dermatomyositis filed by the Company's subsidiary, Priovant Therapeutics, and has granted the NDA Priority Review. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing with the U.S. Securities and Exchange Commission made by the Company, 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.

Exhibit No.	Description of Exhibit
99.1	Press Release, dated March 3, 2026.
104	Cover Page Interactive Data File (embedded with Inline XBRL document).

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.

ROIVANT SCIENCES LTD.

By: /s/ Keyur Parekh
Name: Keyur Parekh
Title: Authorized Signatory

Dated: March 3, 2026

Exhibit 99.1

Priovant Announces FDA Acceptance and Priority Review of New Drug Application for Brepocitinib in Dermatomyositis

- FDA assigns PDUFA target action date in the third quarter of calendar year 2026 with launch expected at the end of September 2026
- Priority Review supported by positive Phase 3 VALOR results, the first positive 52-week placebo-controlled trial in dermatomyositis
- If approved, brepocitinib would represent the first targeted therapy approved for dermatomyositis

DURHAM, NC, March 03, 2026 (GLOBE NEWSWIRE) -- Priovant Therapeutics today announced that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for brepocitinib for the treatment of dermatomyositis (DM) and has granted the application Priority Review. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date in the third quarter of calendar year 2026. The company expects to launch the drug in the United States at the end of September 2026.

The FDA grants Priority Review to applications for medicines that, if approved, provide significant improvements in the safety or effectiveness of the treatment of a serious condition. The Priority Review designation was supported by the significant unmet medical need in dermatomyositis and the results from the Phase 3 VALOR study evaluating brepocitinib in DM. VALOR (N=241) was the longest and largest interventional dermatomyositis trial to date and the first-ever positive 52-week placebo-controlled study in DM.

“The dermatomyositis patient and medical communities have been waiting for decades for novel innovative therapeutics that directly target the underlying disease biology, and it is incredibly exciting to have the finish line in sight for the potential first FDA approval of a targeted therapy for this debilitating disease,” said Dr. Ruth Ann Vleugels, M.D., M.P.H., M.B.A., Heidi and Scott C. Schuster Distinguished Chair in Dermatology, Founding Director of the Autoimmune Skin Disease Center and Connective Tissue Disease Clinics at Mass General Brigham and Program Director of the Dermatology-Rheumatology Fellowship at Harvard Medical School. “Dermatomyositis patients are suffering and urgently need better treatment options. The brepocitinib Phase 3 data suggests that this therapy has the potential to meaningfully improve these patients’ quality of life and function with a once-daily oral therapy. I am thrilled regarding this major step forward in our ability to care for our patients with dermatomyositis."

DM patients experience significant disease burden from muscle disease, skin disease, and frequent dependency on chronic high-dose steroids. Accumulated organ damage from uncontrolled chronic inflammation and the burdens of chronic steroid dependency contribute to high rates of comorbidities among DM patients on current standard of care.

“The acceptance of our NDA for brepocitinib in dermatomyositis represents meaningful progress towards our goal of bringing a potentially transformational therapy to dermatomyositis patients who urgently need better treatment options,” said Ben Zimmer, CEO of Priovant. “We are committed to working closely with the FDA through their review to make this drug available for patients as quickly as possible.”

About the Phase 3 VALOR Study

The VALOR study was a global Phase 3 trial enrolling 241 subjects with dermatomyositis across 90 sites. Subjects were randomized 1:1:1 to brepocitinib 30 mg, brepocitinib 15 mg, and placebo. Brepocitinib 30 mg demonstrated statistically significant and clinically meaningful improvement compared to placebo on the primary endpoint of myositis Total Improvement Score (TIS) at Week 52. TIS is a composite endpoint of 6 measures of disease activity. Benefit compared to placebo was seen as early as Week 4 and sustained at every visit thereafter through the end of the one-year double-blind treatment period. Brepocitinib 30 mg also demonstrated statistically significant and clinically meaningful improvement compared to placebo on all nine Key Secondary endpoints evaluated, including measurements of skin disease, muscle disease, and steroid sparing. More than two thirds of brepocitinib 30mg patients achieved a Total Improvement Score of at least 40 (TIS40), twice the minimum clinically important difference. More than half achieved this TIS40 threshold while also achieving steroid dependency of ≤2.5 mg/day.

The VALOR trial enrolled a broad-based DM population including patients with prior history of benign or malignant neoplasm and patients with multiple cardiovascular risk factors. Serious infections in the study were increased in brepocitinib 30 mg compared to placebo; these events resolved with medical management, and brepocitinib treatment was completed in most cases. New or recurrent malignancy, cardiovascular events, and thromboembolic events in the study occurred more frequently in the placebo arm than the brepocitinib 30 mg arm. The brepocitinib safety database across all studies includes over 2,000 patients and subjects and suggests a safety profile similar to approved JAK and TYK2 inhibitors.

About Priovant

Priovant Therapeutics is a biotechnology company dedicated to developing novel therapies for autoimmune diseases with high morbidity and few available treatment options. The company's lead asset is brepocitinib, a dual selective inhibitor of TYK2 and JAK1. Through dual TYK2/JAK1 inhibition, brepocitinib distinctively suppresses key cytokines linked to autoimmunity—including type I IFN, type II IFN, IL-6, IL-12, and IL-23—with a single, targeted, once-daily oral therapy. Brepocitinib recently generated positive Phase 3 data in dermatomyositis. The New Drug Application for brepocitinib in dermatomyositis is under review at FDA. Brepocitinib is also being evaluated in a Phase 3 program in non-infectious uveitis and recently generated positive Phase 2 data in cutaneous sarcoidosis, with a Phase 3 study to begin in calendar year 2026. Priovant Therapeutics is a Roivant (Nasdaq: ROIV) company.

Forward-Looking Statements

This press release contains forward-looking statements. Statements in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are usually identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and variations of such words or similar expressions. The words may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act.

Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, and statements that are not historical facts, including statements about the clinical and therapeutic potential of our product candidate, the availability and success of topline results from our ongoing clinical trials and any commercial potential of our product candidate following applicable regulatory approvals. In addition, any statements that refer to projections, forecasts or other characterizations of future events, results or circumstances, including any underlying assumptions, are forward-looking statements. Actual results may differ materially from those contemplated in these statements due to a variety of risks, uncertainties and other factors.

Although we believe that our plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, those risks set forth in the Risk Factors section of the filings made by Roivant Sciences Ltd. with the U.S. Securities and Exchange Commission. Moreover, we operate in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this press release, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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