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 27, 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
(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. ☐

Item 7.01 Regulation FD Disclosure.

On August 27, 2026, Roivant Sciences Ltd. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration had approved the New Drug Application for LISRAYA™ (brepocitinib) for the treatment of adults with dermatomyositis submitted by the Company's subsidiary, Priovant Therapeutics, Inc. 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 SEC 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 August 27, 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: August 27, 2026

Exhibit 99.1

Roivant Announces FDA Approval of LISRAYA™ (brepocitinib) for Adults with Dermatomyositis; Now Available in the U.S.

- LISRAYA represents the first major therapeutic innovation in decades for adults with dermatomyositis (DM), a debilitating systemic autoimmune disease
- LISRAYA is a once-daily pill that directly targets key immune pathways implicated in dermatomyositis pathogenesis
- LISRAYA demonstrated robust efficacy on multiple measures of DM disease activity, accompanied by substantial steroid-sparing benefits, in the largest dermatomyositis clinical trial ever conducted
- LISRAYA is available immediately in the U.S.
- Eligible patients may pay as little as $0 per month through the LISRAYA My Compass Support program.
- Roivant will host an investor call to discuss these updates tomorrow, August 28, 2026, at 8:00 a.m. ET.

BASEL, Switzerland and LONDON and NEW YORK, August 27, 2026 (GLOBE NEWSWIRE) -- Roivant (Nasdaq: ROIV) today announced that the U.S. Food and Drug Administration (FDA) has approved LISRAYA™ (brepocitinib) 30 mg for the treatment of adults with dermatomyositis (DM). LISRAYA is a pill taken once daily.

DM is a rare systemic autoimmune disease characterized by progressive muscle weakness and extensive, painful, and pruritic skin lesions. DM significantly impairs patients' quality of life through physical disability, pain from both muscle and skin disease, cutaneous disfigurement, skin sensitivity to light and touch, and high levels of dependency on chronic high-dose steroids.

“We are hopeful the approval of LISRAYA in DM will be the first of many for brepocitinib, and will provide an important new treatment option for these patients.” said Matt Gline, CEO of Roivant. “I'm proud of the work our teams have put in to get here, and we remain focused on advancing our late-stage programs in non-infectious uveitis, cutaneous sarcoidosis, and lichen planopilaris — all also diseases where patients have been waiting a long time for better options.”

LISRAYA, a first-in-class TYK2/JAK1 inhibitor, is the first and only targeted therapy approved for dermatomyositis. LISRAYA is proven to provide a wide array of efficacy benefits for adult DM patients, including improvements in skin disease, muscle strength, physical function, and overall disease burden, alongside substantial steroid-sparing benefit. LISRAYA can be prescribed by healthcare professionals in the United States effective immediately. Prescriptions can be submitted at lisrayahcp.com/enroll. Full prescribing information is available at lisrayahcp.com/pi.

“Dermatomyositis affects nearly every aspect of a patient’s life, causing physical disability, disfiguring skin disease, pain, itch, and a profound loss of independence and sense of self,” said Ruth Ann Vleugels, MD, MPH, MBA, 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 Professor of Dermatology at Harvard Medical School. “For many decades, the treatment of dermatomyositis has relied on chronic steroids, non-specific immunomodulators, and intravenous immunoglobulin—therapies not targeted to the underlying disease pathobiology. The approval of LISRAYA marks a turning point for patients living with dermatomyositis. For the first time, I am thrilled to be able to offer my patients a targeted, once-daily oral medicine that delivers meaningful benefit across muscle, skin, and overall disease activity while simultaneously reducing reliance on systemic corticosteroids.”

LISRAYA’s approval follows the landmark Phase 3 VALOR trial, the largest DM trial ever conducted.

In the VALOR trial, benefits on the primary endpoint, the myositis Total Improvement Score (a composite measure designed to capture improvement across multiple disease domains), were seen as early as Week 4, increased over time, and were sustained to the end of the 52-week study. Most patients treated with LISRAYA were able to achieve both moderate or better improvement on the Total Improvement Score and minimal or no steroid use by the end of the study (55%, compared to 30% on placebo), underscoring LISRAYA’s ability to simultaneously improve disease symptoms and reduce steroid dependency. Among patients receiving LISRAYA who were taking ≥7.5 mg/day (prednisone-equivalent) of oral corticosteroids at baseline, 62% tapered to minimal or no steroid use (≤2.5 mg/day) by the end of the 52-week study, compared with 38% on placebo; 45% came off corticosteroids entirely, compared with 29% on placebo.

LISRAYA also demonstrated benefit on independent measures of skin disease and muscle strength, and, critically, on endpoints that directly capture patients’ own experience living with dermatomyositis. When asked to rate the overall activity of their disease, patients receiving LISRAYA reported more than four times as much improvement as patients on placebo. On a measure of everyday function – including pain and core activities of daily living such as getting dressed, climbing stairs, and running errands – patients treated with LISRAYA achieved clinically meaningful improvement, while those receiving placebo worsened, highlighting LISRAYA’s ability to restore greater independence and personal agency to DM patients’ lives.

The most common adverse reactions for patients on LISRAYA in the VALOR trial were upper respiratory tract infection, headache, fatigue, urinary tract infection, nausea, bronchitis, arthralgia, diarrhea, back pain, fall, influenza, and acne. See important LISRAYA safety information below and full safety information, including boxed warning, at lisrayahcp.com/pi.

Primary results from the VALOR trial were published in the *New England Journal of Medicine* in March 2026, with additional skin-specific secondary endpoints published in *JAMA Dermatology* in August 2026.

LISRAYA is indicated for the treatment of dermatomyositis in adults. It can be used for adult DM patients with no restrictions based on their level of disease activity, clinical presentation, or prior treatment experience. LISRAYA can be used as an alternative therapy or add-on therapy to non-targeted DM treatments used today, depending on specific patient needs. Notably, the Phase 3 VALOR study evaluated the efficacy and safety of LISRAYA across patients on a wide array of different combinations of background therapies, including no background therapy.

Priovant is committed to helping patients access LISRAYA as quickly as possible. LISRAYA is available through a limited distribution network of specialty pharmacies. Patients can enroll in LISRAYA My Compass Support, which offers personalized assistance from a dedicated Patient Access Liaison, including help with insurance coverage, financial assistance programs, and ongoing support throughout the treatment journey. Through My Compass Support, eligible patients may pay as little as $0 per month for LISRAYA. Patients can enroll in My Compass Support at lisraya.com/enrollment.

“Today’s approval of LISRAYA marks a historic moment for the dermatomyositis community and reflects years of extraordinary work and sacrifice by the team at Priovant, our partners, and, above all, the investigators and patients who participated in the brepocitinib development program,” said Ben Zimmer, Chief Executive Officer of Priovant. “I am thrilled that adults with dermatomyositis finally have a fundamentally new treatment option – one specifically designed to target the biology of their disease and shown to meaningfully improve how patients feel and function in their daily lives.”

FDA approval of LISRAYA follows the agency’s prior granting of Priority Review and Orphan Drug Designation. Priority Review is reserved for medicines that, if approved, would provide significant improvements in safety or efficacy for treatment of a serious condition.

LISRAYA IMPORTANT SAFETY INFORMATION and INDICATION AND USAGE

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), and THROMBOSIS

INDICATIONS AND USAGE

LISRAYA (brepocitinib) is indicated for the treatment of adults with dermatomyositis (DM).

Limitations of Use

Not recommended for use in combination with other JAK inhibitors, other TYK2 inhibitors, or biologic DMARDs.

WARNINGS and PRECAUTIONS:

Serious infections. Patients treated with LISRAYA are at increased risk of developing serious bacterial, fungal, viral, and opportunistic infections that may lead to hospitalization or death.

Reported infections with use of Janus kinase (JAK) inhibitors, including LISRAYA:

- Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Evaluate and test patients for latent and active TB infection prior to and during LISRAYA treatment. If positive, treat for TB. Monitor all patients for active TB during treatment including patients who tested negative for a latent TB infection prior to LISRAYA treatment.
- Invasive fungal infections. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.
- Bacterial, viral (including herpes zoster), and other infections due to opportunistic pathogens.

Avoid use of LISRAYA in patients with an active, serious infection, including localized infections. Consider the risks and benefits of LISRAYA in patients with chronic or recurrent infection prior to initiating treatment. Closely monitor patients for signs and symptoms of infection during and after treatment with LISRAYA. If a serious infection occurs, interrupt LISRAYA treatment until the infection resolves or is adequately treated.

Mortality. A higher rate of all-cause mortality, including sudden cardiovascular death, was observed with another Janus kinase (JAK) inhibitor when compared to tumor necrosis factor (TNF) blockers in patients with rheumatoid arthritis (RA) 50 years of age and older with at least one cardiovascular risk factor. LISRAYA is not approved for use in patients with RA.

Malignancy. Malignancies have occurred in patients treated with LISRAYA. A higher rate of malignancies (excluding non-melanoma skin cancer), lymphomas, and lung cancers was observed with another JAK inhibitor when compared to TNF blockers in patients with RA. LISRAYA is not approved for use in patients with RA. Patients who are current or past smokers are at additional increased risk.

Major Adverse Cardiovascular Events (MACE). Major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) have occurred in patients treated with LISRAYA. A higher rate of MACE was observed with another JAK inhibitor when compared to TNF blockers in patients with RA 50 years of age and older with at least one cardiovascular risk factor. LISRAYA is not approved for use in patients with RA. Patients who are current or past smokers are at additional increased risk. Discontinue LISRAYA in patients who have experienced a myocardial infarction or stroke.

Thrombosis. Thromboses, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated for inflammatory conditions with JAK inhibitors, including LISRAYA. Many of these adverse reactions were serious and some resulted in death. A higher rate of thromboses was observed with another JAK inhibitor when compared to TNF blockers in patients with RA 50 years of age and older with at least one cardiovascular risk factor. LISRAYA is not approved for use in patients with RA. Avoid LISRAYA in patients who may be at risk of thrombosis. If symptoms of thrombosis occur, discontinue LISRAYA, promptly evaluate, and appropriately treat.

Hypersensitivity. LISRAYA is contraindicated in patients with known hypersensitivity to brepocitinib or any of its excipients. Hypersensitivity reactions were reported in patients receiving LISRAYA. Some events were serious.

Gastrointestinal Perforations. Gastrointestinal perforation has been reported in patients treated with JAK inhibitors, including LISRAYA. Monitor LISRAYA-treated patients who may be at risk for gastrointestinal perforation.

Hypoglycemia in Patients with Diabetes. LISRAYA may cause hypoglycemia in patients with diabetes. Hypoglycemia, including severe hypoglycemia, has been reported following initiation of JAK inhibitors in patients with diabetes. During treatment with LISRAYA, consider increased monitoring of blood glucose as clinically indicated in patients with diabetes.

Laboratory Abnormalities. LISRAYA has been associated with lab abnormalities including neutropenia, lymphopenia, anemia, increases in lipid parameters, and liver enzyme elevations.

Immunizations. Avoid use of live vaccines during or immediately prior to LISRAYA therapy initiation. Prior to initiating LISRAYA treatment, update immunizations, including prophylactic varicella zoster or herpes zoster vaccinations, according to current immunization guidelines.

Embryofetal Toxicity. Based on findings in animal studies, LISRAYA may cause fetal harm when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to starting treatment. Advise pregnant women and females of reproductive potential of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with LISRAYA and for 3 days following the last dose.

ADVERSE REACTIONS
The most common adverse reactions occurring in ≥5% of DM subjects and ≥2% greater than placebo were upper respiratory tract infection, headache, fatigue, urinary tract infection, nausea, bronchitis, arthralgia, diarrhea, back pain, fall, influenza, and acne.

SPECIAL POPULATIONS
Pregnancy. Based on findings in animal studies, LISRAYA may cause fetal harm when administered to a pregnant woman. Available data from LISRAYA use in pregnant women are insufficient to establish a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

Lactation. There are no data on the presence of brepocitinib in human milk, the effects on the breastfed infant, or the effects on milk production.

Hepatic Impairment. LISRAYA is not recommended in patients with severe hepatic impairment.

Renal Impairment. LISRAYA is not recommended in patients with severe renal impairment.

Please see the Full Prescribing Information, including BOXED WARNING, and Medication Guide.

Investor Conference Call Information

Roivant will host a live conference call and webcast at 8:00 a.m. ET on Friday, August 28, 2026, to report discuss these updates.

To access the conference call by phone, please register online using this registration link. The presentation and webcast details will also be available under "Events & Presentations" in the Investors section of the Roivant website at https://investor.roivant.com/news-events/events. The archived webcast will be available on Roivant's website after the conference call.

About Roivant

Roivant (Nasdaq: ROIV) is a biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Roivant's pipeline includes LISRAYA™ (brepocitinib), a potent small molecule inhibitor of JAK1 and TYK2 FDA-approved for the treatment of dermatomyositis in adult patients and also in late stage development for the treatment of non-infectious uveitis, cutaneous sarcoidosis and lichen planopilaris; IMVT-1402, a fully human monoclonal antibody targeting FcRn in development across several IgG-mediated autoimmune indications; and mosliciguat, an inhaled sGC activator in development for pulmonary hypertension associated with interstitial lung disease. We advance our pipeline by creating nimble subsidiaries or "Vants" to develop and commercialize our medicines and technologies. For more information, visit www.roivant.com.

Roivant 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 and product candidates, the availability and success of topline results from our ongoing clinical trials, any commercial potential of our product and product candidates following applicable regulatory approvals and the outcome of any pending litigation. 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 our filings 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.

Contacts:

- Investors: Keyur Parekh at keyur.parekh@roivant.com
- Media: Stephanie Lee at stephanie.lee@priovant.com
- Adult dermatomyositis patients: 1-888-736-9788 or mycompasssupport@priovant.com