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): October 21, 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 October 21, 2026, Roivant Sciences Ltd. (the "Company") issued a press release announcing positive results from the Phase 3 CLARITY program evaluating brepocitinib in non-infectious uveitis ("NIU") conducted by its subsidiary, Priovant Therapeutics, Inc. ("Priovant"). 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 October 21, 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: October 21, 2026

Exhibit 99.1

Roivant and Priovant Announce Positive Results in CLARITY-1 and CLARITY-2 Phase 3 Trials for Brepocitinib in Non-Infectious Uveitis (NIU)

- Brepocitinib 45 mg once-daily achieved statistically significant benefit compared to placebo on the primary and all key secondary endpoints for each of CLARITY-1 and CLARITY-2, the two identical Phase 3 trials comprising the CLARITY program in NIU
- Median time to treatment failure for brepocitinib patients was greater than 48 weeks in both studies, compared with ~12 weeks on placebo in each study ($p<0.0001$ in both studies), including 40 weeks of steroid-free treatment, setting a new bar for time to failure and steroid-sparing benefit in NIU
- Pooled across the CLARITY studies, 62% of patients on brepocitinib achieved steroid-free quiescence at Week 48, compared with 20% on placebo ($p<0.0001$), with similar results in each study
- Of patients that entered the CLARITY studies (pooled) with macular edema, 42% of eyes on brepocitinib achieved resolution of macular edema at Week 48, compared with 4.8% on placebo ($p<0.0001$), with similar results in each study
- The magnitude and breadth of benefit observed across every ranked endpoint, compared with results reported in registrational trials of existing NIU therapies, suggest brepocitinib has the potential to be the most effective systemic, non-steroid treatment option for NIU
- Safety data consistent with prior brepocitinib clinical trials; no new safety signals or findings
- Priovant intends to file a supplemental New Drug Application (sNDA) for brepocitinib for the treatment of NIU in the first half of calendar year 2027
- Roivant will host an investor call to discuss these updates today, October 21, 2026, at 8:00 a.m. ET

BASEL, Switzerland and LONDON and NEW YORK and DURHAM, N.C., October 21, 2026 (GLOBE NEWSWIRE) – Roivant (Nasdaq:ROIV) and Priovant Therapeutics today announced positive results from the Phase 3 CLARITY program evaluating brepocitinib in non-infectious uveitis (NIU). Brepocitinib met the primary endpoint for both the CLARITY-1 and CLARITY-2 studies. Brepocitinib also achieved statistically significant and clinically meaningful benefit on all key secondary endpoints, including measurements of sustained steroid-free quiescence at Week 48, chorioretinal vascular leakage, resolution of macular edema and patient-reported visual functioning. These results were achieved despite a substantially more aggressive steroid taper than precedent NIU trials.

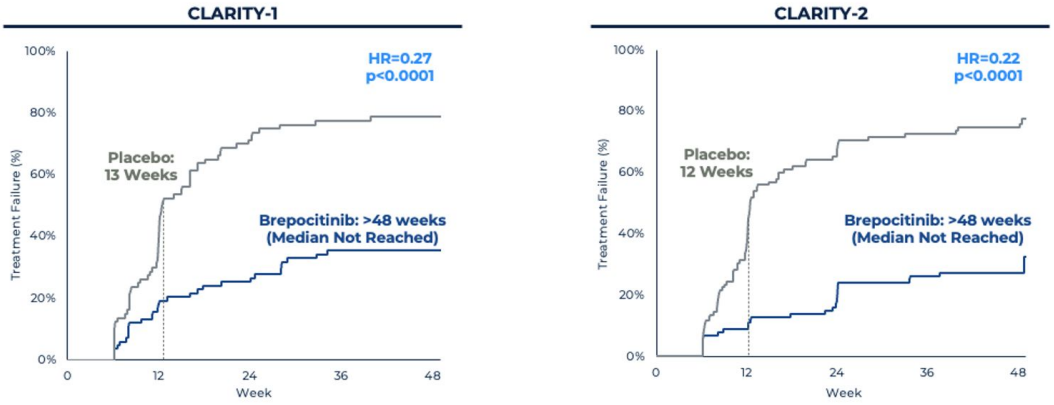
“Today marks a potential turning point for the field of uveitis and for the patients and physicians who have waited nearly a decade for a new systemic, non-steroid treatment option. The phenomenal results from the Phase 3 CLARITY program suggest that brepocitinib could meaningfully change how we treat non-infectious uveitis across multiple etiologies,” said Quan Dong Nguyen, MD, MSc, FAAO, FARVO, FASRS, Professor of Ophthalmology, Professor of Medicine (Immunology/Rheumatology), and Professor of Pediatrics (Rheumatology) at the Byers Eye Institute and Stanford University School of Medicine, President of the International Ocular Inflammation Society (IOIS), and Executive Vice President of the Foster Ocular Immunology Society (FOIS). “Even with a much faster taper of oral prednisone, patients treated with brepocitinib in CLARITY demonstrated highly differentiated benefits across the primary and all key secondary endpoints, including quiescence, resolution of macular edema and improvement in chorioretinal inflammation. This is the kind of outcome that can redefine expectations for an entire field. To see this breadth of benefit across disease control, macular edema and visual functioning is tremendously exciting for those of us who care for these patients.”

NIU, a debilitating ocular inflammation, is one of the leading causes of blindness among the working age population. Undertreated NIU can result in permanent vision loss. NIU is frequently associated with ocular pain, floaters and visual impairment across multiple domains (acuity, peripheral vision, color recognition, ability to focus on moving objects, night vision, etc.) that can interfere with everyday activities including reading the newspaper, driving, socializing, working and independent self-care. NIU is estimated to affect 70,000 to 190,000 adults in the United States.

CLARITY Study Design and Data

The CLARITY program enrolled 371 patients across two identical studies, CLARITY-1 and CLARITY-2. Patients were randomized 1:1 to once-daily brepocitinib 45 mg or placebo for a 48-week double-masked treatment period. All patients received an 8-week oral corticosteroid (OCS) regimen of 60 mg/day for 2 weeks followed by a mandatory 6-week steroid taper to zero. The primary endpoint was time to treatment failure, assessed from Week 6 through Week 48.

Time to treatment failure in CLARITY-1 and CLARITY-2 (Kaplan-Meier estimates, brepocitinib vs. placebo) is captured below:



Brepocitinib demonstrated consistent benefits on preventing treatment failure across key subgroups, including intermediate, posterior, and panuveitis; patients with and without prior TNFi experience; and multiple etiologies of uveitis, including idiopathic disease, birdshot chorioretinopathy, and sarcoidosis.

Pre-specified multiplicity controlled secondary endpoints in the CLARITY trials included sustained steroid-free quiescence, improvement in chorioretinal vascular leakage as assessed through wide-field fluorescein angiography (FA), resolution of macular edema, and improvement in patient-reported visual functioning (NEI VFQ-25 overall composite score).

Results on the primary and key secondary endpoints are captured below:

	CLARITY-1 (N=166)			CLARITY-2 (N=204)		
	Brepocitinib 45 mg	Placebo	Delta*	Brepocitinib 45 mg	Placebo	Delta*
Hazard Ratio for Treatment Failure vs. Placebo (95% CI)	0.27 (0.17–0.43)	--	P<0.0001	0.22 (0.14–0.34)	--	P<0.0001
Cumulative Incidence of Treatment Failure at Week 48	35.4%	78.7%	Δ 43.3%; P<0.0001	32.4%	77.8%	Δ 45.4%; P<0.0001
Steroid-Free Quiescence in Both Eyes at Week 48	58.8%	19.8%	Δ 38.1%; P<0.0001	64.4%	19.4%	Δ 45.2%; P<0.0001
Achievement of FA Response (≥ 30% Reduction from Baseline) at Week 48 Among Eyes With FA Score > 5 at Baseline	39.4%	8.6%	Δ 31.3%; P<0.0001	54.9%	7.2%	Δ 49.8%; P<0.0001
Resolution of Macular Edema at Week 48 Among Eyes with Macular Edema at Baseline	40.4%	2.1%	Δ 33.3%; P=0.0041	42.6%	7.0%	Δ 40.1%; P=0.0002
Achievement of ≥ 5-point Improvement in NEI VFQ-25 Overall Composite Score from Baseline at Week 48, Among Subjects with Baseline ≤ 95	36.4%	13.7%	Δ 21.9%; P=0.0013	40.4%	14.1%	Δ 24.5%; P=0.0003

**Deltas account for covariates*
Efficacy analyses exclude one subject who was randomized but did not receive any doses of masked study drug.

Safety and Regulatory Submissions

Brepocitinib was generally well tolerated during the treatment period. Most events were mild or moderate in severity, and only 3% of participants discontinued treatment due to an AE. The observed safety profile in the trials was consistent with the known safety profile of brepocitinib, with no new safety signals observed.

Priovant intends to file a supplemental New Drug Application (sNDA) for brepocitinib for treatment of NIU in the first half of calendar year 2027.

“The breadth and magnitude of benefit seen in the CLARITY studies position brepocitinib to potentially set a new standard for the treatment of non-infectious uveitis,” said Ben Zimmer, CEO of Priovant. “With LISRAYA now commercially available for adults with dermatomyositis, we see NIU as the potential next pillar of a leading rare disease immunology franchise. I would like to thank all of the investigators and patients who participated in the CLARITY trials, without whom this moment would not be possible.”

Investor Conference Call Information

Roivant will host a live conference call and webcast at 8:00 a.m. ET on Wednesday, October 21, 2026, to discuss the Phase 3 results for brepocitinib in non-infectious uveitis. 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.

Roivant will also host an investor day on Wednesday, December 9, 2026. To attend the event in person or by webcast, please register online using this registration link.

About Priovant

Priovant Therapeutics is a biotechnology company dedicated to developing and commercializing novel therapies for autoimmune diseases with high morbidity and few available treatment options. The company's commercial product, LISRAYA™ (brepocitinib) is the first and only targeted oral therapy approved for the treatment of adults with dermatomyositis. See important LISRAYA safety information, including boxed warning, at lisrayahcp.com/pi. Brepocitinib, a first-in-class TYK2/JAK1 inhibitor, also recently generated positive Phase 3 data in non-infectious uveitis (NIU). Brepocitinib is under evaluation in a Phase 3 program in cutaneous sarcoidosis, and a Phase 2b/3 program in lichen planopilaris. These potential indications have not been approved by the FDA. Priovant Therapeutics is a Roivant (Nasdaq: ROIV) company.

About Roivant

Roivant (Nasdaq: ROIV) is a commercial-stage 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, the timing of potential regulatory approvals for our product and product candidates, 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.

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