UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): November 27, 2023

Roivant Sciences Ltd.

(Exact Name of Registrant as Specified in 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 communication 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 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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 November 27, 2023, Roivant Sciences Ltd. issued a press release announcing that its subsidiary Priovant's Phase 2 study evaluating oral brepocitinib in adult patients with moderate to severe active lupus did not meet its primary endpoint. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference into this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press Release dated November 27, 2023
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/ Matt Maisak
Name: Matt Maisak
Title: Authorized Signatory

Dated: November 27, 2023

Exhibit 99.1

Roivant and Priovant Announce Results from Phase 2 Study of Oral Brepocitinib in Systemic Lupus Erythematosus

- Oral brepocitinib failed to meet its primary endpoint of Systemic Lupus Erythematosus Responder Index (SRI-4) change of 4 at Week 52
- Priovant plans to continue progressing the program in indications outside of Systemic Lupus Erythematosus (SLE) given the drug's favorable safety and tolerability profile, six other positive phase 2 studies, and active arm performance in this study
- Priovant expects to announce topline results from the Phase 2 POC study of brepocitinib in non-infectious uveitis (NIU) in the first quarter of calendar year 2024 and topline results from the Phase 3 trial in dermatomyositis (DM) in calendar year 2025

BASEL, LONDON, and NEW YORK, November 27, 2023 – Roivant (Nasdaq: ROIV) and Priovant today announced the Phase 2 study evaluating oral brepocitinib in adult patients with moderate to severe active lupus did not meet its primary endpoint of Systemic Lupus Erythematosus Responder Index change of 4 (SRI-4) at Week 52. Priovant plans to disclose the study data at a future date.

"We saw some of the highest SRI-4 responder rates ever observed in a lupus study in the active arm of this trial, along with a favorable safety and tolerability profile. Unfortunately, we also saw the highest placebo response rate observed in any significant SLE study, and as such it was not possible to truly assess the impact of the drug, or to establish sufficient differentiation from other therapies in lupus patients. While we do not plan to progress the program in SLE, these results continue to support our view that oral brepocitinib is a highly active agent with a good safety profile, and we remain enthusiastic about brepocitinib's ability to produce meaningful clinical benefit in non-infectious uveitis and dermatomyositis in Priovant's ongoing trials, as well as in many other potential indications" said Matt Gline, CEO of Roivant. "Roivant and Priovant would like to extend our gratitude to the patients who participated in this trial, their caregivers, and the trial investigators that enabled this study and these insights."

Priovant expects to announce topline results from its own studies, the Phase 2 POC study of brepocitinib in non-infectious uveitis (NIU) in the first quarter of calendar year 2024 and the Phase 3 trial in dermatomyositis (DM) in calendar year 2025. Oral brepocitinib has demonstrated statistically significant clinically meaningful benefit in six completed placebo-controlled Phase 2 studies in psoriasis, psoriatic arthritis, alopecia areata, hidradenitis suppurativa, ulcerative colitis, and Crohn's disease.

About Roivant

Roivant is a commercial-stage biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Today, Roivant's pipeline includes VTAMA®, a novel topical approved for the treatment of psoriasis and in development for the treatment of atopic dermatitis; batoclimab and IMVT-1402, fully human monoclonal antibodies targeting the neonatal Fc receptor ("FcRn") in development across several IgG-mediated autoimmune indications; brepocitinib, a novel TYK2/JAK1 inhibitor in late stage development for dermatomyositis and other autoimmune conditions, in addition to other clinical stage molecules. We advance our pipeline by creating nimble subsidiaries or "Vants" to develop and commercialize our medicines and technologies. Beyond therapeutics, Roivant also incubates discovery-stage companies and health technology startups complementary to its biopharmaceutical business. For more information, 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 products and product candidates, the availability and success of topline results from our ongoing clinical trials and any commercial potential of our products and product candidates. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements.

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
Roivant Investor Relations
ir@roivant.com

Media
Stephanie Lee
Roivant Sciences
stephanie.lee@roivant.com