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): June 22, 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 Market**
Redeemable warrants, each whole warrant exercisable for one Common Share	**ROIVW**	**The Nasdaq Global 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 June 22, 2023, Roivant Sciences Ltd. issued a press release announcing positive results from the chronic period of the TUSCANY-2 Phase 2b study of RVT-3101, a once-monthly subcutaneously administered anti-TL1A antibody. 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	Roivant Sciences Ltd. Press Release, dated June 22, 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: June 22, 2023

Exhibit 99.1

Roivant Reports Chronic Period Data for RVT-3101 from the TUSCANY-2 Phase 2b Study in Ulcerative Colitis, Demonstrating Improved Efficacy from the Induction to Chronic Period

- This is the first-ever long-duration data reported for an anti-TL1A antibody
- At the expected Phase 3 once-monthly subcutaneous dose in the overall population, RVT-3101 treatment resulted in improved Clinical Remission[1] (36% at week 56 vs. 29% at week 14) and Endoscopic Improvement[2] (50% vs. 36%)
- At the expected Phase 3 once-monthly subcutaneous dose in the biomarker positive population, RVT-3101 treatment resulted in improved Clinical Remission (43% at week 56 vs. 33% at week 14) and Endoscopic Improvement (64% vs. 47%)
- Across all patients dosed in the chronic period, RVT-3101 treatment produced clinically meaningful efficacy results, which improved between the induction and chronic period across multiple endpoints
- Across all doses and patient groups, RVT-3101 was well tolerated and showed a favorable safety profile
- There was no negative impact of antidrug antibodies (ADAs) on short-term or long-term efficacy results of RVT-3101 across all patients treated, and 0% of patients had neutralizing antibodies (NAbs) at week 56 at the expected Phase 3 dose
- TUSCANY-2 is among the largest Phase 2b studies conducted in moderate to severe ulcerative colitis with 245 patients treated
- Roivant will host a conference call to discuss results at 8 a.m. EDT on Thursday, June 22, 2023

BASEL, Switzerland and LONDON and NEW YORK and BOSTON, June 22, 2023 – Roivant Sciences (Nasdaq: ROIV) today announced positive results from the chronic period of the TUSCANY-2 Phase 2b study of RVT-3101, a once-monthly subcutaneously administered anti-TL1A antibody.

TUSCANY-2 is a large, global, randomized, double-blind, placebo-controlled dose-ranging Phase 2b study to investigate the efficacy, safety and pharmacokinetics of RVT-3101 in adult participants with moderate to severe ulcerative colitis. TUSCANY-2 is a 56-week study in which the key efficacy analyses from the induction period comparing different doses of RVT-3101 against placebo were measured at week 14. Key outcomes for the chronic period, in which all patients received RVT-3101, were measured at week 56. Patients who received RVT-3101 in the induction period were preassigned to receive either the same or a lower dose in the chronic period. Roivant reported positive data for the induction period of the study in January 2023.

[1] Clinical Remission for RVT-3101 is defined as an endoscopic subscore ≤1, ≥1-point decrease from baseline to achieve a stool frequency sub score of ≤1, and rectal bleeding subscore = 0

[2] Endoscopic Improvement for RVT-3101 is defined as an endoscopic subscore ≤1

The results from the chronic period of TUSCANY-2 are as follows:

For all patients receiving the expected Phase 3 dose in both the induction and chronic periods

- 36% Clinical Remission at week 56 (compared with 29% at week 14)
- 50% Endoscopic Improvement at week 56 (compared with 36% at week 14)
- 21% Endoscopic Remission at week 56 (compared with 11% at week 14)

For patients who tested positive for a prespecified biomarker and received the expected Phase 3 dose in both the induction and chronic periods

- 43% Clinical Remission at week 56 (compared with 33% at week 14)
- 64% Endoscopic Improvement at week 56 (compared with 47% at week 14)
- 36% Endoscopic Remission at week 56 (compared with 13% at week 14)

Safety profile

- Well-tolerated through 56 weeks across all doses with no impact of immunogenicity on clinical efficacy or safety results

These results continue to support RVT-3101's potential as a first-in-class anti-TL1A antibody, demonstrating sustained efficacy across a broad dose range measured at 56 weeks. At the expected Phase 3 dose, RVT-3101 offers improved efficacy results. These results were further enhanced in the roughly 60% of patients selected by a prospectively defined biomarker which had been identified in the earlier Phase 2a TUSCANY study.

"We were already extremely pleased by the induction data we reported in January. Our expectations for this chronic data were categorically exceeded, with significant improvements seen in patients receiving the expected Phase 3 dose across all key efficacy metrics at week 56 versus at week 14. This effect was even more pronounced in patients who are biomarker positive. We also saw that the clinical remission reported for week 14 was maintained in the vast majority of patients, which, if confirmed in Phase 3, has the potential to transform the treatment paradigm for IBD – currently marked by low remission rates and poor persistence of effect," said Matt Gline, CEO of Roivant.

Investor Call

A conference call and webcast will be held at 8 a.m. EDT on Thursday, June 22, 2023, to discuss the chronic period results for RVT-3101. To access the conference call by phone, please register online using this registration link. The presentation and webcast details are also 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 Sciences

Roivant's mission is to improve the delivery of healthcare to patients by treating every inefficiency as an opportunity. Roivant develops transformative medicines faster by building technologies and developing talent in creative ways, leveraging the Roivant platform to launch "Vants" – nimble and focused biopharmaceutical and health technology companies.

Roivant Sciences 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. Such 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.

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