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): January 4, 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 par value 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 January 4, 2023, Roivant Sciences Ltd. (the "Company") issued a press release announcing interim data from the induction period of TUSCANY-2, a large global Phase 2b study of subcutaneous RVT-3101 for the treatment of ulcerative colitis. 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 January 4, 2023
104	Cover Page Interactive Data File (embedded with Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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: January 4, 2023

Exhibit 99.1

Roivant Announces Statistically Significant and Clinically Meaningful Results from the Induction Period of TUSCANY-2, a Large Global Phase 2b Study of Subcutaneous RVT-3101 for the Treatment of Ulcerative Colitis in Both the Overall and the Biomarker Positive Patient Populations

- RVT-3101 demonstrated statistically significant and clinically meaningful efficacy at each dose tested
- Across all patients treated with RVT-3101, the clinical remission and endoscopic improvement rates were 32% and 40%, respectively. Similar results were observed at the expected Phase 3 dose
- At the expected Phase 3 dose, among patients who were positive for a biomarker that was prospectively defined in TUSCANY-2, clinical remission and endoscopic improvement rates were 40% and 56%, respectively. Approximately 60% of patients were identified as positive for this biomarker
- At the expected Phase 3 dose, among patients who had been previously treated with biologics and who were biomarker positive, clinical remission and endoscopic improvement rates were 41% and 56%, respectively
- Across all doses and patient groups, RVT-3101 was well tolerated and showed a favorable safety profile
- Roivant will host a conference call to discuss results at 8AM ET on Wednesday, January 4, 2023

BASEL, Switzerland, LONDON, NEW YORK and BOSTON, Jan. 4, 2023 (GLOBE NEWSWIRE) — Roivant Sciences (Nasdaq: ROIV) today announced positive results from the induction period of the TUSCANY-2 Phase 2b study of RVT-3101 (previously PF-06480605), a once monthly subcutaneously administered anti-TL1A antibody which demonstrated statistically significant and clinically meaningful efficacy results at each dose tested. RVT-3101 was well tolerated and showed a favorable safety profile. RVT-3101 will progress into registrational studies as a potential best-in-class and first-in-class subcutaneous therapy in ulcerative colitis.

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 245 adult participants with moderate to severe ulcerative colitis. TUSCANY-2 is a 52-week study, with a 12-week induction period comparing different doses of RVT-3101 against placebo, and a 40-week chronic therapy period during which all subjects receive RVT-3101. The chronic therapy period is still ongoing with data expected in 1H 2023. During the induction period, patients were treated monthly with subcutaneous RVT-3101 at 50 mg, 150 mg, and 450 mg without a loading dose required. RVT-3101 demonstrated statistically significant and clinically meaningful efficacy at each dose tested.

The results from the induction period of TUSCANY-2 are as follows:[1]

Efficacy results for the pooled drug cohort

All patients:

- 32% achieved clinical remission (modified Mayo) (p=0.01, 21% delta compared to 12% placebo)
- 40% achieved endoscopic improvement (p=0.01, 21% delta compared to 19% placebo)

[1] One-sided p-values were computed in accordance with Pfizer prespecified statistical analysis plan. Statistical significance considered to be a p-value ≤ 0.025. Values that are not significant are marked “NS.” Placebo-adjusted delta values may not exactly match the difference between gross and placebo values due to rounding.

Patients who were biomarker positive:

- 37% achieved clinical remission (modified Mayo) (p=0.02, 27% delta compared to 10% placebo)
- 51% achieved endoscopic improvement (p=0.002, 41% delta compared to 10% placebo)

Efficacy results at the expected Phase 3 dose

All patients:

- 31% achieved clinical remission (modified Mayo) (p=0.01, 20% delta compared to 12% placebo)
- 40% achieved endoscopic improvement (p=0.01, 22% delta compared to 19% placebo)

Patients who were biomarker positive:

- 40% achieved clinical remission (modified Mayo) (p=0.02, 30% delta compared to 10% placebo)
- 56% achieved endoscopic improvement (p=0.0005, 46% delta compared to 10% placebo)

Patients who were biomarker positive and biologic-experienced:

- 41% achieved clinical remission (modified Mayo) (p=0.03 (NS), 41% delta compared to 0% placebo)
- 56% achieved endoscopic improvement (p=0.005, 56% delta compared to 0% placebo)

Safety profile

- Across all doses and patient groups, RVT-3101 was well tolerated and showed a favorable safety profile

These results demonstrated best-in-indication potential for RVT-3101 across the full population of moderate to severe ulcerative colitis patients, with enhanced efficacy in patients who were positive for a prospectively defined biomarker regardless of prior biologic experience. RVT-3101 has the potential to be both a highly efficacious first- or second-line treatment and a preferred precision medicine in the approximately 60% of patients who are biomarker positive.

“TUSCANY-2 is among the largest and most robust Phase 2b studies ever conducted in ulcerative colitis. We are incredibly pleased with these initial results demonstrating not only high-end efficacy and a favorable safety profile in the overall population but also enhanced efficacy in patients who are biomarker positive, including patients who were previously treated with biologics. We are excited to bring an innovative therapy to millions of patients in need of more efficacious treatments and for the potential to bring relief to patients who have failed biologic therapies,” said Matt Gline, CEO of Roivant.

Roivant expects to report data from the chronic therapy period of TUSCANY-2 in 1H 2023.

Investor call

A conference call and webcast will be held at 8AM ET on Wednesday, January 4, 2023, to discuss 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. For more information, please visit www.roivant.com.

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. 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