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): April 2, 2024

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.

Data Release

On April 2, 2024, Roivant Sciences Ltd. ("Roivant") issued a press release announcing positive NEPTUNE study results for brepocitinib in non-anterior non-infectious uveitis, as well as authorization by Roivant's board of directors for an up to $1.5 billion common share repurchase program, including the repurchase of all common shares held by Sumitomo Pharma Co., Ltd. ("Sumitomo") for approximately $648.4 million. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference into this Item 8.01.

As described in the press release, Roivant will host a conference call and webcast to discuss the NEPTUNE results and its share repurchase program at 8:00 a.m. EDT on April 2, 2024.

Share Repurchase

Roivant's board of directors has authorized a common share repurchase program, allowing for repurchases of Roivant common shares in an aggregate amount of up to $1.5 billion (excluding fees and expenses). The repurchase program will be funded with available cash and cash equivalents on hand and does not have an expiration date. The timing and total amount of common shares to be repurchased will depend on several factors, including the market price of the company's common shares, general business, macroeconomic and market conditions and other investment opportunities. Under the repurchase program, purchases may be conducted through open market transactions, tender offers or privately negotiated transactions, including the use of trading plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended.

Pursuant to the share repurchase program, on April 2, 2024 Roivant entered into a share repurchase agreement with Sumitomo to repurchase all 71,251,083 common shares held by Sumitomo at a purchase price per share of $9.10, for an aggregate purchase price of approximately $648.4 million. The repurchase transaction with Sumitomo is expected to close on or about April 4, 2024.

The share repurchase program may be suspended or discontinued at any time. There can be no assurances as to how many additional common shares the company will repurchase under the program, if any, or at what prices any purchases will be made.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press Release dated April 2, 2024
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: April 2, 2024

Exhibit 99.1

Roivant Announces Positive NEPTUNE Study Results for Brepocitinib in NIU, as well as Board Authorization for up to $1.5 Billion Share Repurchase Program, Including Repurchase of Entire Sumitomo Pharma Stake for $648 Million

- Roivant's board of directors has approved a share repurchase program for up to $1.5 billion of the company's common shares, including an agreed repurchase of the entire Sumitomo Pharma stake for $648 million
- Sumitomo Pharma repurchase reduces shares outstanding by 9%
- In the Phase 2 NEPTUNE study of once-daily oral brepocitinib in non-infectious uveitis (NIU), the 45 mg results represent the best Treatment Failure rates observed to date among active NIU studies measuring this registrational endpoint
- 29% of subjects receiving brepocitinib 45 mg and 44% of subjects receiving brepocitinib 15 mg met the pre-specified primary efficacy endpoint of Treatment Failure at week 24 (lower failure rates reflect greater treatment benefit). The Treatment Failure rate from disease activity (discontinuations censored) was 18% in the brepocitinib 45 mg arm
- All secondary efficacy endpoints were also positive and dose responsive, including measurements of potential benefit on prevention and treatment of uveitic macular edema
- NEPTUNE represents the seventh positive Phase 2 study for brepocitinib with over 1,400 subjects and patients treated with brepocitinib in clinical trials. Brepocitinib was generally safe and well-tolerated in the study; no new safety and tolerability signals were identified
- Brepocitinib is well positioned to support a potential multi-blockbuster franchise in specialty autoimmunity with an ongoing pivotal study in dermatomyositis on track to read out in calendar year 2025 and expected initiation of a pivotal program in NIU in the second half of calendar year 2024
- Roivant will host an investor call to discuss the updates at 8 a.m. EDT on Tuesday, April 2, 2024

BASEL, Switzerland and LONDON and NEW YORK, April 2, 2024 (GLOBE NEWSWIRE) – Roivant (Nasdaq: ROIV) and Priovant Therapeutics today announced positive results from the Phase 2 study (NEPTUNE) evaluating brepocitinib in non-anterior non-infectious uveitis (NIU), showing the strongest efficacy data in NIU observed to date. Roivant also announced that its board of directors has authorized a share repurchase program for up to $1.5 billion of the company's common shares, including the repurchase of all 71.3 million shares held by Sumitomo Pharma at a purchase price of $9.10 per share. The aggregate purchase price for the Sumitomo Pharma transaction is approximately $648.4 million and will reduce Roivant's shares outstanding as of February 9, 2024 by approximately 9%.

"The striking NIU data underscore Roivant's continued commitment to developing effective medicines in underserved indications with high unmet need, such as for these patients who are at risk of blindness. We are extremely pleased to share these positive data. We are also pleased to announce our authorized share repurchase program, and our agreed repurchase of all shares owned by Sumitomo Pharma. This transaction along with further potential buybacks reduces shareholder concentration and efficiently retires shares, increasing our continuing shareholders' exposure to developments in NIU and to the rest of our upcoming clinical data and company progress," said Matt Gline, CEO of Roivant.

The NEPTUNE study enrolled 26 subjects with active NIU who were randomized 2:1 to brepocitinib 45 mg once daily or brepocitinib 15 mg once daily. Patients, physicians, and the study team were blinded to dose. All subjects received a 60 mg/day prednisone burst at study entry for two weeks and were tapered off prednisone per protocol by week 8 (six-week steroid taper). Subjects were evaluated for Treatment Failure, a registrational composite endpoint comprising multiple measures of ocular inflammation and visual acuity, as well as discontinuation due to intercurrent events or initiation of rescue therapy. The study's primary efficacy endpoint was the Treatment Failure rate at week 24.

At week 24, 29% (5/17) of subjects in the brepocitinib 45 mg arm and 44% (4/9) of subjects in the brepocitinib 15 mg arm met Treatment Failure criteria, with lower failure rates reflecting greater treatment benefit. The Treatment Failure rate from disease activity (discontinuations censored) was 18% in the brepocitinib 45 mg arm. These observed results represent approximately twice the observed benefit as seen in the corresponding registrational study for the only approved non-steroidal therapy in NIU.

All week 24 secondary efficacy endpoints, including haze grades, visual acuity, and macular thickness, were also positive and dose responsive. Of patients in the brepocitinib 45 mg arm who met the threshold for uveitic macular edema at baseline, 43% achieved resolution of macular edema by week 24. No patients in the brepocitinib 45 mg arm who entered the study without macular edema developed macular edema by week 24.

Safety and tolerability were consistent with prior clinical studies of brepocitinib, with no new safety or tolerability signals identified. Brepocitinib has been dosed in over 1,400 subjects and patients with a safety profile that appears consistent with approved and widely prescribed JAK inhibitors. Additional safety and efficacy data will be presented at a future medical conference.

“Non-infectious uveitis is a devastating disease that can lead to severe visual impairment and contribute to tens of thousands of cases of legal blindness in the United States each year, including many instances of irreversible blindness,” said Quan Dong Nguyen, MD, MSc, FARVO, FASRS, NEPTUNE investigator and Professor of Ophthalmology at the Byers Eye Institute, and Professor of Medicine and Pediatrics at Stanford University School of Medicine. “Current treatment options provide inadequate benefits to many patients; thus, novel pharmacotherapeutic agents with better efficacy and more convenient methods of administration are urgently needed. Brepocitinib’s striking results on multiple endpoints of clinical significance position the drug to become a potentially transformative once-daily oral therapy for this debilitating disease and reinforce the distinctive mechanistic benefits of dual TYK2/JAK1 inhibition for highly inflammatory autoimmune diseases with multiple pathogenic cytokines, such as non-infectious uveitis.”

“The NEPTUNE study was designed to minimize likelihood of false signals of benefit, by tapering patients with active disease from 60 mg/day of prednisone to 0 mg/day in just six weeks, more than twice as fast as steroid tapers in precedent studies,” said Ben Zimmer, CEO of Priovant. “Against that backdrop, we are thrilled to see a failure rate of only 29% in the brepocitinib 45 mg arm, better than any precedent study was able to achieve even with more lenient tapers. The magnitude and consistency of dose-dependent benefit across multiple independent measurements of inflammation, visual acuity, and macular edema give us high confidence heading into Phase 3. The results further point to a potentially highly differentiated product profile for brepocitinib in NIU—an orphan indication with high prevalence, severe morbidity, and few other therapies approved or in development.”

Priovant intends to initiate a Phase 3 program in NIU in the second half of calendar year 2024. The company would like to thank all of the investigators and patients who participated in the NEPTUNE study.

The ongoing Phase 3 study evaluating brepocitinib in dermatomyositis is expected to be fully enrolled in the third calendar quarter of 2024, with data expected in calendar year 2025.

Share Repurchase Program & Sumitomo Pharma Repurchase

Roivant's board of directors has authorized a common share repurchase program, allowing for repurchases of Roivant common shares in an aggregate amount of up to $1.5 billion. The repurchase program will be funded with available cash and cash equivalents on hand and does not have an expiration date. The timing and total amount of common shares to be repurchased will depend on several factors, including the market price of the company's common shares, general business, macroeconomic and market conditions, and other investment opportunities. Under the repurchase program, purchases may be conducted through open market transactions, tender offers or privately negotiated transactions, including the use of trading plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended.

Pursuant to the share repurchase program, on April 2, 2024, Roivant entered into a share repurchase agreement with Sumitomo Pharma to repurchase all 71,251,083 common shares held by Sumitomo Pharma at a purchase price per share of $9.10, for an aggregate purchase price of approximately $648.4 million. The repurchase transaction with Sumitomo Pharma is expected to close on or about April 4, 2024.

The repurchase program may be suspended or discontinued at any time. There can be no assurances as to how many additional common shares the company will repurchase under the program, if any, or at what prices any purchases will be made.

Investor Call

An investor call and webcast will be held at 8 a.m. EDT on April 2, 2024, to discuss the Phase 2 NEPTUNE study results for brepocitinib in NIU and Roivant's share repurchase program. 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 Priovant

Priovant Therapeutics is a biotechnology company dedicated to developing novel therapies for autoimmune diseases with high morbidity and few available treatment options. The company's lead asset is brepocitinib, a dual selective inhibitor of TYK2 and JAK1. Through dual TYK2/JAK1 inhibition, brepocitinib is able to distinctively suppress key cytokines linked to autoimmunity—including type I IFN, type II IFN, IL6, IL12, and IL23—with a single, targeted therapy. Brepocitinib has generated positive data in seven Phase 2 studies with oral once-daily administration. Brepocitinib is currently being evaluated in a Phase 3 program for dermatomyositis and is entering a Phase 3 program for non-infectious uveitis.

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, non-infectious uveitis, 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 potential share repurchases, 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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