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): December 20, 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 7.01. Regulation FD Disclosure.

On December 20, 2023, Roivant Sciences Ltd. (the "Company") issued a press release announcing initial data from Immunovant's proof-of-concept Phase 2 clinical trial in Graves' disease. 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 the Exchange Act, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, or the Securities Act. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing with the U.S. Securities Exchange Commission, or the SEC, made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On December 20, 2023, the Company's subsidiary, Immunovant, Inc., announced that results from the initial cohort of patients in an ongoing 24-week Phase 2 clinical trial of batoclimab in patients with Graves' disease meaningfully exceeded 50% response rates.

This Phase 2 proof-of-concept trial is an open-label study to assess the safety and efficacy of batoclimab in Graves' disease. Patients who are hyperthyroid despite treatment with an anti-thyroid medication (ATD) for more than 12 weeks are being enrolled to receive once-weekly subcutaneous (SC) injections of 680 mg batoclimab for 12 weeks followed by once-weekly SC injections of 340 mg batoclimab for 12 weeks. Treatment response is defined as normalization of T3 and T4 hormone levels without increasing ATD dose. The primary and secondary outcome measurements of the trial are being measured at weeks 12 and 24. This design allowed for efficacy assessments between two distinct ranges of IgG reductions.

Consistent with studies of batoclimab in other indications, 680 mg administered SC in the initial cohort demonstrated potential best-in class IgG reduction, up to 87%, with a mean IgG reduction of 81% after 12 weeks of treatment. The 340 mg IgG reductions were lower. A similar dose response was observed for anti-TSHR autoantibodies, with deeper reductions observed following treatment with 680 mg of SC batoclimab as compared to 340 mg of SC batoclimab. In addition, across a range of clinical parameters, numerically higher responses were observed following treatment with 680 mg of batoclimab as compared to treatment with 340 mg of batoclimab. These parameters included the percentage of patients whose ATD dose was reduced and the percentage of patients whose ATD was discontinued. Batoclimab was generally well tolerated with no new safety signals observed in the initial data set.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press Release dated December 20, 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: December 20, 2023

Exhibit 99.1

Roivant Reports Positive Initial Phase 2 Results for Batoclimab in Graves' Disease

NEW YORK, December 20, 2023 – Immunovant, Inc. (Nasdaq: IMVT), a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases, today announced that results from the initial cohort of patients in an ongoing 24-week Phase 2 clinical trial of batoclimab in patients with Graves' disease meaningfully exceeded 50% response rates.

This Phase 2 proof-of-concept trial is an open-label study to assess the safety and efficacy of batoclimab in Graves' disease. Patients who are hyperthyroid despite treatment with an anti-thyroid medication (ATD) for more than 12 weeks are being enrolled to receive once-weekly subcutaneous (SC) injections of 680 mg batoclimab for 12 weeks followed by once-weekly SC injections of 340 mg batoclimab for 12 weeks. Treatment response is defined as normalization of T3 and T4 hormone levels without increasing ATD dose. The primary and secondary outcome measurements of the trial are being measured at weeks 12 and 24. This design allowed for efficacy assessments between two distinct ranges of IgG reductions.

Consistent with studies of batoclimab in other indications, 680 mg administered SC in the initial cohort demonstrated potential best-in class IgG reduction, up to 87%, with a mean IgG reduction of 81% after 12 weeks of treatment. The 340 mg IgG reductions were lower. A similar dose response was observed for anti-TSHR autoantibodies, with deeper reductions observed following treatment with 680 mg of SC batoclimab as compared to 340 mg of SC batoclimab. In addition, across a range of clinical parameters, numerically higher responses were observed following treatment with 680 mg of batoclimab as compared to treatment with 340 mg of batoclimab. These parameters included the percentage of patients whose ATD dose was reduced and the percentage of patients whose ATD was discontinued. Batoclimab was generally well tolerated with no new safety signals observed in the initial data set.

"We believe the enrolled population is unlikely to spontaneously remit and therefore a greater than 50% response rate is encouraging," said Pete Salzmann, M.D., chief executive officer at Immunovant. "While preliminary, these data suggest there is a dose response on efficacy between a regimen that produces 60-70% IgG reductions, such as 340 mg of batoclimab, and a regimen that produces 80% IgG reductions. We are excited to have what we believe to be the only option across the anti-FcRn field of a simple SC injection to produce this profile. We believe there is a high unmet need in second line Graves' disease and are enthusiastic about the addressable market size here. While this trial is ongoing, we intend to focus our future development in Graves' on IMVT-1402, with plans expected to be announced later in 2024."

About Immunovant, Inc.
Immunovant, Inc. is a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases. As a trailblazer in anti-FcRn technology, the Company is developing innovative, targeted therapies to meet the complex and variable needs of people with autoimmune diseases. For additional information on the Company, please visit www.immunovant.com.

Immunovant Forward-Looking Statements

This press release contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "can," “may,” “might,” “will,” “would,” “should,” “expect,” “believe,” “estimate,” “design,” “plan,” "intend," and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include Immunovant’s expectations regarding the timing, design, and results of clinical trials of its product candidates; Immunovant's plan to develop batoclimab and IMVT-1402 across a broad range of autoimmune indications; and potential benefits of batoclimab’s and IMVT-1402’s unique product attributes and potential best-in-class profile including IgG reduction. All forward-looking statements are based on estimates and assumptions by Immunovant’s management that, although Immunovant believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Immunovant expected. Such risks and uncertainties include, among others: initial results or other preliminary analyses or results of early clinical trials may not be predictive final trial results or of the results of later clinical trials; the timing and availability of data from clinical trials; the timing of discussions with regulatory agencies, as well as regulatory submissions and potential approvals; the continued development of Immunovant’s product candidates, including the timing of the commencement of additional clinical trials ; Immunovant’s scientific approach, clinical trial design, indication selection, and general development progress; future clinical trials may not confirm any safety, potency, or other product characteristics described or assumed in this press release; any product candidate that Immunovant develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; Immunovant’s product candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of global factors, such as the post-COVID-19 environment, geopolitical tensions, and adverse macroeconomic conditions on Immunovant’s business operations and supply chain, including its clinical development plans and timelines; Immunovant’s business is heavily dependent on the successful development, regulatory approval and commercialization of batoclimab and IMVT-1402; Immunovant is at an early stage of development for IMVT-1402 and in various stages of clinical development for batoclimab; and Immunovant will require additional capital to fund its operations and advance batoclimab and IMVT-1402 through clinical development. These and other risks and uncertainties are more fully described in Immunovant’s periodic and other reports filed with the Securities and Exchange Commission (SEC), including in the section titled “Risk Factors” in Immunovant’s Form 10-Q filed with the SEC on November 9, 2023, and Immunovant’s subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Immunovant undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

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. 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," "suggest," "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, plans to develop our product candidates for particular indications, 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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