UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): September 9, 2024

Roivant Sciences Ltd.

(Exact name of Registrant as Specified in Its Charter)

Bermuda	**001-40782**	**98-1173944**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

7th Floor
50 Broadway
London SW1H 0DB
United Kingdom
(Address of Principal Executive Offices)

+44 207 400-3347
(Registrant's Telephone Number, Including Area Code)

Former Name or Former Address, if Changed Since Last Report: Not Applicable

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:

☐ Written communications 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	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 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 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 September 9, 2024, Roivant Sciences Ltd. (the "Company") issued a press release providing an update on the Graves' Disease development program at Immunovant. 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, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. 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 made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated September 9, 2024.
104	Cover Page Interactive Data File (embedded within the 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 thereunto duly authorized.

ROIVANT SCIENCES LTD.

Date: September 9, 2024

By: /s/ Matt Maisak
Name: Matt Maisak
Title: Authorized Signatory

Exhibit 99.1

Roivant Provides Update on Graves' Disease Development Program

- High dose batoclimab achieved 76% response rate in patients uncontrolled on antithyroid drugs (ATDs) at week 12
- High dose batoclimab achieved 56% ATD-free response rate in patients uncontrolled on ATDs at week 12
- Strong correlation observed between degree of IgG lowering and clinical outcomes yields potential best-in-class and first-in-class opportunity for IMVT-1402 in Graves' Disease (GD)
- Real world claims data indicates 25-30% of Graves' Disease patients per year are uncontrolled on ATDs with minimal to no existing therapeutic options representing an attractive commercial opportunity with limited competition
- IND cleared with initiation of IMVT-1402 pivotal trial in GD expected by calendar year end

NEW YORK, Sept. 9, 2024 (GLOBE NEWSWIRE) -- **Immunovant, Inc. (Nasdaq: IMVT)**, a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases, today reported positive results from the Phase 2a trial of batoclimab in Graves' Disease. Immunovant also disclosed data from several proprietary market research studies that showed a consistent unmet need among ATD treated patients who are intolerant to, uncontrolled on or relapsed after ATDs. Finally, Immunovant also announced alignment with the U.S. Food & Drug Administration (FDA) and Investigational New Drug Application (IND) clearance with initiation of a pivotal trial of IMVT-1402 in GD expected by December 31, 2024.

As previously disclosed, the batoclimab phase 2a trial in uncontrolled GD enrolled patients who were hyperthyroid despite ATD therapy. Participants in the trial received 12 weeks of high dose batoclimab, 680 mg weekly by subcutaneous injection (SC) followed by 12 weeks of lower dose batoclimab, 340 mg weekly SC. At the end of the first 12 weeks, participants experienced a mean IgG reduction of 77% leading to a 76% Response rate (defined as T3 and T4 falling below the upper limit of normal (ULN) without increasing the ATD dose). In addition, by the end of 12 weeks of higher dose batoclimab, 56% achieved an ATD-Free Response (defined as T3 and T4 falling below the ULN and the patient simultaneously tapering completely off their ATD). Despite benefiting from a lower starting IgG level after 12 weeks of 680mg therapy, during Weeks 13 to 24, the lower 340mg dose of batoclimab resulted in mean IgG reduction of 65% (vs. 77% on 680mg dose) with a correspondingly lower responder rate of 68%. In addition, a lower ATD-Free Response rate of 36% was also observed in the second 12 weeks. Finally, patients who achieved at least a 70% IgG reduction at the end of the trial had nearly a threefold higher ATD-Free Response rate than those who did not (60% vs. 23%).

"We are thrilled to share these updates today which we believe validate a large and important degree of unmet medical need in patients uncontrolled on ATDs and which we believe demonstrate strong response rates in this same population," said Pete Salzmann, M.D., chief executive officer of Immunovant. "We find the correlation between clinical response and IgG lowering impressive and believe this creates not only a potential first-in-class but also a potential best-in-class opportunity for IMVT-1402. We are very pleased to have aligned with the FDA on a pivotal trial design that we expect to initiate by the end of the year."

Webcast Details

Immunovant will host a webcast at 8:00 a.m. ET today to discuss these updates. **Please click here to register for the event.** The live webcast will also be available under the News & Events section of Immunovant's website. A replay of the event and presentation will be available immediately following the event.

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 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," "anticipate," "intend," and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include, but are not limited to, statements regarding the potential benefits of IMVT-1402's unique product attributes and potential first-in-class and best-in-class profile; the expected initiation of a pivotal trial of IMVT-1402 in GD and the timing thereof; and the potential commercial opportunity of IMVT-1402 as a treatment for GD. 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: Immunovant may not be able to protect or enforce its intellectual property rights; initial results or other preliminary analyses or results of early clinical trials may not be predictive of 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 number and 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 macroeconomic and geopolitical factors 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 IMVT-1402 and/or batoclimab; Immunovant is at various stages of clinical development for IMVT-1402 and batoclimab; and Immunovant will require additional capital to fund its operations and advance IMVT-1402 and batoclimab 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 August 6, 2024, 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; IMVT-1402 and batoclimab, fully human monoclonal antibodies targeting the neonatal Fc receptor ("FcRn") in development across several IgG-mediated autoimmune indications; and brepocitinib, a potent small molecule inhibitor of TYK2 and JAK1 for the treatment of dermatomyositis and non-infectious uveitis, 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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