

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 21, 2025

Roivant Sciences Ltd.

(Exact Name of Registrant as Specified in Charter)

Bermuda
(State or Other Jurisdiction of Incorporation)

001-40782
(Commission File Number)

98-1173944
(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, \$0.000000341740141 par value 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 April 21, 2025, Roivant Sciences Ltd. (the “Company”) issued a press release announcing changes to the leadership team at its subsidiary, Immunovant, Inc. (“Immunovant”), including the retirement of Immunovant’s CEO, changes to Immunovant’s board of directors and the expanded development of IMVT-1402 in two new indications. 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 of Exhibit
99.1	Press Release, dated April 21, 2025.
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/ Keyur Parekh

Name: Keyur Parekh

Title: Authorized Signatory

Dated: April 21, 2025

Immunovant Announces Next Phase of Growth with Roivant Including Changes to its Leadership Team and Additional Indications Sjögren's Disease (SjD) and Cutaneous Lupus Erythematosus (CLE) for IMVT-1402

- Eric Venker, M.D. (currently President and COO of Roivant) appointed as CEO of Immunovant and Tiago Girao appointed as CFO of Immunovant
- Pete Salzmann, M.D. retired from his role as Immunovant CEO and Director
- Leadership change is part of a broader strategic transition with Roivant increasing operational involvement and strategic oversight of Immunovant
- IND cleared for a potentially registrational program for IMVT-1402 in SjD, its fifth and potentially best-in-class indication with positive in-class competitor data from Phase 2 studies suggesting a correlation between depth of IgG reduction and degree of clinical improvement; study expected to initiate in summer 2025
- Proof-of-concept study of IMVT-1402 initiated in CLE, its sixth and potentially first-in-class and best-in-class indication, based on promising efficacy data from patients dosed with IMVT-1402 as part of an open label case study program
- Current cash balance provides runway for announced indications through Graves' Disease readout expected in 2027
- Roivant will host an investor call to discuss the updates at 8 a.m. EDT on Monday, April 21, 2025

NEW YORK, April 21, 2025 (GLOBE NEWSWIRE) -- Immunovant, Inc. (Nasdaq: IMVT), a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases, today announced next phase of growth including changes to its leadership team and the expanded development of IMVT-1402 into two new indications, SjD and CLE.

Eric Venker, M.D., Roivant's President and an Immunovant Director, has been appointed as Immunovant's CEO. Dr. Venker brings over two decades of clinical practice and operational experience to the company and will continue to serve on Immunovant's Board of Directors. As part of this planned transition, Pete Salzmann, M.D. retired from his position as Immunovant CEO and Director. Renee Barnett stepped down from her position as Immunovant CFO; she is succeeded by Tiago Girao, formerly Telavant CFO. Immunovant has announced these changes in conjunction with a broader strategic transition as development activities begin to conclude for batoclimab and ramp up for IMVT-1402, with increased Roivant alignment and the announcement of two additional indications today.

“I want to extend my deepest thanks to Pete Salzmann for his leadership of the company through a period of significant growth and transformation. Under Pete, Immunovant has shown compelling efficacy data in clinical trials for batoclimab in Myasthenia Gravis, Chronic Inflammatory Demyelinating Polyneuropathy, Graves’ Disease and Thyroid Eye Disease, while developing the IMVT-1402 program to a total of six indications, now including Sjögren’s and CLE,” said Eric Venker, M.D., CEO of Immunovant and President of Roivant. “I am incredibly excited to lead Immunovant into the next leg of its journey with a renewed focus on clinical execution across IMVT-1402 indications, all of which are potentially best-in-class or first-in-class and if successful, will have an enormous impact on both the trajectory of the company and the anti-FcRn treatments available for patients.”

“I am retiring from Immunovant with a deep sense of pride in what the company has achieved in the last six years. It has been an honor to build the company and advance its mission with an esteemed group of colleagues,” said Pete Salzmann, M.D. “I am also incredibly pleased that the Board has appointed a highly qualified successor, and I feel confident in the future of the company under Eric Venker’s leadership.”

In addition to the leadership team changes noted above, George Migausky has stepped down from the Immunovant board of directors, and Robert Susman and Jacob Bauer have joined the board, effective April 18, 2025.

Investor Relations Update and Investor Call

As a part of this leadership change and strategic realignment, Roivant will lead all Immunovant investor relations activity. Please direct all Immunovant investor and media queries to the contacts listed in this release.

Roivant will host a live conference call and webcast at 8:00 a.m. EDT on Monday, April 21, 2025, to discuss these updates at Immunovant. To access the conference call by phone, please register online using this registration link. The presentation and webcast details will also be 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 Sjögren’s Disease

Sjögren’s disease is a chronic autoimmune disease characterized by lymphocytic infiltration of the salivary and lacrimal glands, associated with severe dryness of the mouth and eyes. Up to one-half of affected individuals also develop extra-glandular involvement in organs such as the joints, skin, lungs, gastrointestinal tract, nervous system, and kidneys. No therapies have been approved specifically for the treatment of Sjögren’s disease. Therapeutic approaches for Sjögren’s disease include both topical and systemic treatments to manage eye and mouth dryness and systemic symptoms. There is a need for the development of novel treatments that target the underlying pathophysiological mechanisms.

About Cutaneous Lupus Erythematosus

CLE is a rare, chronic skin disease where IgG autoantibodies and immune complexes are observed to play a critical role in disease pathophysiology. CLE patients experience painful skin lesions, itching, burning, alopecia, and potential scarring. There remains a high unmet need in CLE with up to 50% of patients not optimally managed with current therapies and no new therapies having been approved in over 50 years. The IND for CLE is now active and a proof-of-concept trial evaluating IMVT-1402 has been initiated.

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.

Cautionary Note Regarding 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 relating to the timing, design, and results of its clinical trials of IMVT-1402, including the number and timing of (a) FDA clearance with respect to IND applications, (b) initiation and readouts from potential registrational programs and clinical trials of IMVT-1402, (c) expected data readouts from IMVT-1402 trials, and (d) Immunovant's plans to develop IMVT-1402 across a broad range of indications including SjD and CLE; the potential benefits of IMVT-1402 and its potential best-in-class and first-in-class profile; Immunovant's expected cash runway; and the implementation and potential benefits of the strategic realignment and Roivant's increased operational involvement and strategic oversight of Immunovant. 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, 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 IMVT-1402 and batoclimab; 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 February 6, 2025, 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 biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Roivant's pipeline includes IMVT-1402 and batoclimab, fully human monoclonal antibodies targeting FcRn in development across several IgG-mediated autoimmune indications; brepocitinib, a potent small molecule inhibitor of TYK2 and JAK1 in development for the treatment of dermatomyositis, non-infectious uveitis and cutaneous sarcoidosis; and mosliciguat, an inhaled sGC activator in development for pulmonary hypertension associated with interstitial lung disease. 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 the clinical and therapeutic potential of our product candidates, the availability and success of topline results from our ongoing clinical trials and any commercial potential of our product candidates following applicable regulatory approvals. In addition, any statements that refer to projections, forecasts or other characterizations of future events, results or circumstances, including any underlying assumptions, are forward-looking statements. Actual results may differ materially from those contemplated in these statements due to a variety of risks, uncertainties and other factors.

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.

Roivant Contacts:

Investors:

Keyur Parekh

keyur.parekh@roivant.com

Media:

Stephanie Lee

stephanie.lee@roivant.com
