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): December 3, 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 December 3, 2024, Roivant Sciences Ltd. (the "Company") issued a press release announcing topline results from Kinevant's Phase 2 RESOLVE-Lung study of namilumab in chronic active pulmonary sarcoidosis. As noted in the press release, namilumab failed to show treatment benefit in patients with chronic active pulmonary sarcoidosis. 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 December 3, 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: December 3, 2024

By: /s/ Keyur Parekh
Name: Keyur Parekh
Title: Authorized Signatory

Exhibit 99.1

Roivant Announces Topline Results from Phase 2 RESOLVE-Lung Study of Namilumab in Chronic Active Pulmonary Sarcoidosis

- Namilumab failed to show treatment benefit in patients with pulmonary sarcoidosis
- Further development of namilumab for the treatment of sarcoidosis will be discontinued

BASEL, Switzerland and LONDON and NEW YORK, December 3, 2024 GLOBE NEWSWIRE) – Kinevant Sciences, a clinical-stage biopharmaceutical company developing new medicines for rare inflammatory and autoimmune diseases, today announced its Phase 2 study failed to show treatment benefit in patients with chronic active pulmonary sarcoidosis. The Phase 2 RESOLVE-Lung study (NCT05314517) evaluated the efficacy and safety of namilumab, an investigational anti-GM-CSF monoclonal antibody administered once-monthly as a subcutaneous injection, in participants with chronic active pulmonary sarcoidosis.

Primary Endpoint Details: Namilumab failed to meet the primary endpoint of proportion of subjects with a Rescue Event during the double-blind period.

Secondary Endpoints Details: Secondary efficacy endpoints, including change in percent predicted forced vital capacity, corticosteroid tapering success, and change in the patient reported King's Sarcoidosis Questionnaire failed to show a treatment benefit consistent with the primary endpoint.

Safety Details: The safety profile of namilumab in RESOLVE-Lung remains similar to previous studies.

With these results, Kinevant will be discontinuing further development of namilumab for the treatment of sarcoidosis. Kinevant is committed to publishing the results of RESOLVE-Lung to inform future sarcoidosis research.

"Although RESOLVE-Lung failed to show a treatment benefit for namilumab, the significant amount of information produced by the study will be tremendously helpful to those in the field who are committed to improving the lives of sarcoidosis patients," said Bill Gerhart, CEO of Kinevant. "I would like to thank all the patients who courageously volunteered to participate in the study, as well as the Kinevant team, industry partners, principal investigators, site staff, and patient advocacy groups who all worked together to successfully conduct this important study for sarcoidosis."

"Risk-taking in clinical development is at the heart of our industry, and core to Roivant's mission of developing new medicines for patients in need. It's evident from our data that the RESOLVE-Lung study was thoughtfully designed and gave us a clear read on the potential benefits of namilumab in this patient population," said Matt Gline, CEO of Roivant. "Unfortunately science is sometimes humbling, and we are proud to have made the attempt, as well as of our successes in other programs this year. We look forward to taking calculated risks on similar programs in the future."

About RESOLVE-Lung

The RESOLVE-Lung study is a Phase 2 randomized, double-blind, placebo-controlled study of namilumab for the treatment of pulmonary sarcoidosis at sites in the U.S. and Europe. The study enrolled 107 patients with pulmonary sarcoidosis considered to have chronic, active disease not well-controlled despite available therapeutic options. Patients in the study received a once-monthly subcutaneous injection of namilumab or placebo (following the initial dosing period) for approximately six months. All patients who complete the 26-week double-blind treatment period were eligible to participate in a 28-week open-label extension treatment period on namilumab.

The primary endpoint of this study was proportion of subjects with a Rescue Event during the double-blind period. Rescue Event was defined as clinically significant worsening of a subject's sarcoidosis requiring treatment, failure to adhere to the protocol defined OCS taper, or premature discontinuation from the study associated with lack of benefit during the double-blind treatment period.

Study eligibility did not require subjects to be on high dose corticosteroids. If subjects were on >5mg/day of oral corticosteroid (OCS) at baseline, they were required to taper down to 5mg/day 8-10 weeks after randomization. If patients were on an immunosuppressive therapy (IST), they were required to stop the IST at randomization. Notably, all subjects enrolled had evidence of active pulmonary sarcoidosis disease, defined as a positive HRCT scan, significant lung inflammation on PET, and moderate to severe self-reported breathlessness.

About Sarcoidosis

Pulmonary sarcoidosis is a lung disease characterized by the presence of granulomas (clumps of immune cells) of unknown etiology that can cause breathlessness, fatigue, and pain. The resulting inflammation, if not effectively treated, can result in lung tissue scarring (fibrosis), lung dysfunction, and eventually lung failure. Approximately 50% of diagnosed patients require chronic therapy to treat symptoms and prevent progression. Oral steroids (e.g., prednisone) and off-label immunosuppressive therapies (e.g., methotrexate) are first- and second-line therapies respectively for sarcoidosis; however, these therapeutic options are often not effective or can be accompanied by serious side effects.

Approximately 200,000 people in the U.S. (and more than 1 million worldwide) are estimated to have sarcoidosis, an immune-mediated inflammatory disease that can affect any organ in the body, with about 90% of cases involving the lung.

About Namilumab

Granulocyte macrophage colony stimulating factor (GM-CSF) is a pro-inflammatory cytokine over-expressed in several inflammatory diseases, including sarcoidosis. GM-CSF mediated pro-inflammatory signaling is thought to play a central role in recruitment of macrophages and monocytes to the lung and to trigger a granulomatous response, including the fusion of macrophages into multinucleated giant cells. Namilumab is an anti-GM-CSF monoclonal antibody formulated to be administered once-monthly as a subcutaneous injection being investigated for the treatment of pulmonary sarcoidosis.

About Roivant

Roivant 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 and non-infectious uveitis; 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.

Contacts:

Investors

Keyur Parekh

keyur.parekh@roivant.com

Media

Stephanie Lee

stephanie.lee@roivant.com