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 10, 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 10, 2024, Roivant Sciences Ltd. (the "Company") issued a press release announcing its previously undisclosed pipeline program mosliciguat, under development at Pulmovant. 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 10, 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 10, 2024

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

Exhibit 99.1

Roivant Unveils New Pipeline Program Mosliciguat, A Potential First-In-Class and Best-In-Category Inhaled Once-Daily Soluble Guanylate Cyclase (sGC) Activator

- Mosliciguat, a potential first-in-class and best-in-category inhaled soluble Guanylate Cyclase (sGC) activator with targeted delivery to the lungs and once-daily administration, is being developed for pulmonary hypertension associated with interstitial lung disease (PH-ILD), which affects ~200,000 patients in the U.S. and Europe; PH-ILD prevalence is meaningfully greater than that of pulmonary arterial hypertension (PAH) with limited to no treatment options
- In the Phase 1b ATMOS study, presented today at the European Respiratory Society (ERS) Congress, a single dose of inhaled mosliciguat in pulmonary hypertension (PH) patients (N=38) led to sustained, clinically meaningful mean-max reductions in pulmonary vascular resistance (PVR) of up to ~38%, one of the highest reductions seen in PH trials to date
- Once-daily dosing via dry powder inhaler (DPI) was generally well-tolerated, with low rates of treatment-emergent adverse events (TEAEs)
- The global Phase 2 "PHocus" study of mosliciguat in ~120 patients with PH-ILD is expected to begin imminently

BASEL, Switzerland and LONDON and NEW YORK, Sep 10, 2024 – Roivant (Nasdaq: ROIV) today announced its previously undisclosed pipeline program mosliciguat, a potential first-in-class, inhaled, once-daily sGC activator with targeted delivery to the lungs via dry powder inhaler, at Pulmovant. Pulmovant presented data from the proof-of-concept Phase 1b ATMOS study during the ERS Congress in Vienna, Austria.

"We believe mosliciguat can transform the lives of patients living with pulmonary hypertension, and I am excited to announce this potential first-in-class and best-in-category therapy. Mosliciguat has the incredibly rare advantage of potential differentiation across three separate key areas - efficacy, safety, and convenience in administration. We are impressed with the data generated so far, particularly the PVR results, and we believe its differentiated mechanism as an sGC activator can have maximal impact on PH-ILD patients, a large population with severe disease, high morbidity and mortality, and few treatment options," said Matt Gline, Roivant's Chief Executive Officer. "Along with the positive Graves' data announcement at Immunovant yesterday, we feel incredibly fortunate to announce another exciting clinical update this week. As promised, we are continuing to expand our existing pipeline and remain laser-focused on clinical execution, with a number of important study readouts and milestones expected in the coming months."

Mosliciguat has been extensively characterized across a robust Phase 1 program with 170 participants dosed to date, including in the ATMOS study, and based on data from these studies has the potential to show differentiation in efficacy, safety and convenience. Mosliciguat's target, sGC, is a key enzyme in the nitric oxide (NO) / cyclic guanosine monophosphate (cGMP) signaling pathway that catalyzes cGMP production leading to increased vasodilation, reduced inflammation and apoptosis, reverse vascular remodeling and anti-fibrotic effects. Unlike sGC stimulators which require reduced heme and NO to exert their effect on sGC, mosliciguat is an sGC activator that works independently of heme and NO. This also allows mosliciguat to potentially retain efficacy in highly oxidative environments typical of PH, where stimulators are expected to lose efficacy given heme is oxidized or removed and NO levels are depleted.

ATMOS was a non-randomized, open-label, dose escalation, proof-of-concept Phase 1b trial that assessed the efficacy, safety, tolerability, and pharmacokinetics of mosliciguat following single dose inhaled administration in participants aged between 18 and 80 years with World Health Organization (WHO) Group 1 PH (pulmonary arterial hypertension (PAH)) or Group 4 PH (chronic thromboembolic pulmonary hypertension (CTEPH)). Overall, 38 patients received mosliciguat in this study. In the per-protocol set of patients (N=20), mosliciguat 1.0, 2.0 and 4.0 mg doses led to mean-max peak reductions in PVR from baseline of -25.9%, -38.1% and -36.3%, respectively, consistently exceeding the predefined ≥ -20% threshold for the primary outcome. Notably, a similar effect on PVR was observed in the pharmacodynamic analysis set (N=37), which included participants both responsive and non-responsive to inhaled NO, suggesting that mosliciguat's novel mechanism of action may allow for broad activity across the spectrum of PH. Data from ATMOS, a proof-of-concept trial of inhaled mosliciguat in untreated PAH or CTEPH was presented during poster session (PS) 31, poster number PA5238, at the ERS Congress today.

Overall, in its Phase 1 development program in 170 healthy volunteers and PH patients, mosliciguat has shown a favorable safety profile, dose-dependent increases in cGMP and a 40-hour half-life supporting convenient dosing. Mosliciguat is unique among inhaled PH therapies, requiring just one puff once per day to deliver its potential best-in-category PVR reductions – all currently approved therapies require multiple puffs, multiple times per day. Mosliciguat is formulated for delivery via DPI, providing greater convenience to patients compared to nebulizers required for many existing inhaled PH therapies. Direct delivery to the lungs also minimizes risk of serious adverse effects seen with systemic vasodilators, such as worsening of oxygenation status. In addition to greater efficacy as evidenced by PVR in ATMOS, a generally favorable safety profile and ease of administration support the potential differentiation for mosliciguat.

Pulmovant will advance the clinical program to assess mosliciguat in its global Phase 2 PHocus study in patients with PH-ILD, a subgroup of Group 3 PH. Approximately 120 patients will be enrolled in the study, which will start imminently. An estimated 200,000 patients across the U.S. and Europe are living with PH-ILD and have limited or no approved treatment options. The PH-ILD prevalence is meaningfully greater than that of PAH, representing an attractive commercial opportunity with limited competition and high unmet patient need.

Roivant created Pulmovant, a wholly-owned Roivant subsidiary, to in-license from Bayer exclusive worldwide rights to develop and commercialize mosliciguat. Bayer received an upfront cash payment of ~$14.0 million, with up to an additional $280 million agreed upon for future development, regulatory and commercial milestone payments, as well as tiered high-single digit sales-based royalties.

Investor Call

A conference call and webcast will be held at 8:00 AM EDT on Tuesday, September 10, 2024, to discuss these updates. Please register here for the event. The live webcast will also be available under the Events & Presentations section of Roivant's website. A replay of the event and presentation will be available immediately following the event.

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; 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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