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): November 12, 2024

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 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 2.02. Results of Operations and Financial Condition.

On November 12, 2024, Roivant Sciences Ltd. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 2024. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth under this "Item 2.02. Results of Operations and Financial Condition" (including the exhibit thereto) shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing made by the Company pursuant to the Securities Act of 1933, as amended, other than to the extent that such filing incorporates by reference any or all of such information by express reference thereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Roivant Sciences Ltd. Press Release, dated November 12, 2024
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/ Matt Maisak
Name: Matt Maisak
Title: Authorized Signatory

Dated: November 12, 2024

Exhibit 99.1

Roivant Reports Financial Results for the Second Quarter Ended September 30, 2024, and Provides Business Update

BASEL, Switzerland and LONDON and NEW YORK, November 12, 2024 – Roivant (Nasdaq: ROIV) today reported its financial results for the second quarter ended September 30, 2024, and provided a business update.

- Brepocitinib 52-week data from the Phase 2 NEPTUNE study in non-infectious uveitis (NIU) showed potential best-in-indication efficacy sustained to one year; first patients enrolled in Phase 3 NIU program
- IMVT-1402 cleared five Investigational New Drug (IND) applications across a range of therapeutic areas and FDA divisions, including the potentially registrational trial for difficult-to-treat rheumatoid arthritis (D2T RA) expected to initiate by March 31, 2025
- Batoclimab proof of concept data in Graves' disease (GD) demonstrate potential of deeper IgG reduction with potent FcRn inhibition to transform treatment for GD patients who are not well controlled on antithyroid drugs (ATDs); initiation of potentially registrational trial to evaluate IMVT-1402 in GD expected by year end
- Mosliciguat, a once-daily inhaled soluble guanylate cyclase (sGC) activator, unveiled as new pipeline program. Mosliciguat Phase 1b data in pulmonary hypertension (PH) patients demonstrated some of the highest pulmonary vascular resistance (PVR) reductions (~38%) in PH trials to date. The global Phase 2 PHocus trial for mosliciguat has been initiated in patients with pulmonary hypertension associated with interstitial lung disease (PH-ILD)
- Roivant continued to return capital through share repurchases with $106M purchased for the quarter, resulting in $754M cumulative share repurchases (inclusive of Sumitomo) through September 30, 2024
- Dermavant transaction with Organon closed on October 28, 2024. At closing, Roivant received $184M in cash, and Organon took on all of Dermavant's remaining outstanding long-term debt, which, inclusive of Dermavant's senior credit facility repaid at closing, had a carrying value of $336M as of September 30, 2024. In addition, Organon will pay Roivant a $75M milestone upon FDA approval for VTAMA in atopic dermatitis, with a target action date in Q1 2025
- Roivant reported consolidated cash, cash equivalents and marketable securities of approximately $5.4B at September 30, 2024

"I am pleased to finish out another quarter with continued clinical execution, including positive data in Graves' Disease and FDA's clearance of INDs in 5 indications at Immunovant," said Matt Gline, CEO of Roivant. "I am also excited today to present the 52-week data from our Phase 2 study of brepocitinib in NIU. The sustained treatment benefits observed further our belief that brepocitinib is a potentially compelling and durable agent for a disease that is poorly treated today. We have a busy year ahead with major data expected in 2025 from Immunovant and Priovant, along with continued execution across other programs."

Recent Developments

- **Immunovant:**
  Endocrinology Program
  In September 2024, Immunovant reported additional positive results from the Phase 2a trial of batoclimab in Graves' Disease. 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. In addition, by the end of 12 weeks of higher dose batoclimab, 56% achieved an ATD-Free Response. 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. 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%). Batoclimab was well tolerated with no new safety signals identified.

In November 2024, additional data on the efficacy and safety of batoclimab in Graves' thyroidal and extrathyroidal disease were presented in an oral presentation at the American Thyroid Association (ATA) 2024 Annual Meeting. These data showed that a 60% response rate (defined as T3 and T4 falling below the upper limit of normal (ULN) without increasing the ATD dose) was achieved by Week 2, demonstrating the rapidity of response to batoclimab 680mg dosed weekly. Meaningful improvements in proptosis and lid aperture were also observed at both Week 12 and Week 24. Pronounced improvements in multiple Thyroid-Related Patient-Reported Outcomes (ThyPRO-39) measurement scales were also observed, with ATD-Free Responders (defined as T3 and T4 falling below the ULN and ceasing all ATD medications) reporting greater improvements than other participants.

Neurology Program
In November 2024, Immunovant announced completion of enrollment for patients included in Period 1 of the Phase 2b trial of batoclimab in CIDP, with data expected by March 31, 2025, to inform the trial design for a potentially registrational program with IMVT-1402.

Rheumatology Program
In November 2024, Immunovant also announced FDA clearance of the IND for IMVT-1402 in D2T RA and expects to initiate a potentially registrational trial by March 31, 2025.

- **Priovant:** In September 2024, Priovant announced receipt of Fast Track designation from FDA for brepocitinib in NIU and enrolled the first patients in the Phase 3 program. New 52-week data from the Phase 2 NEPTUNE study of brepocitinib in NIU showed potential best-in-indication efficacy sustained to one year. Treatment failure rate in the 45 mg dose arm was 35% at week 52 vs. 29% at week 24. Treatment failure rate in the 15 mg dose arm was 56% vs. 44% at week 24. In each treatment arm only one additional patient failed from week 24 to 52. Other important efficacy measurements at week 52 were consistent with the week 24 data, including measurements of retinal vascular leakage and prevention and treatment of macular edema. Safety and tolerability were consistent with prior clinical studies of brepocitinib, with no new safety or tolerability signals identified. Brepocitinib has been dosed in over 1,400 subjects and patients with a safety profile that appears consistent with approved and widely prescribed JAK inhibitors.

- **Pulmovant:** In September 2024, Roivant unveiled mosliciguat, a potential first-in-class and best-in-category inhaled once-daily sGC activator. Mosliciguat is being developed for PH-ILD, which affects ~200,000 patients in the U.S. and Europe with limited or no treatment options.

  In September 2024, Pulmovant also presented data from the Phase 1b ATMOS study showing a single dose of inhaled mosliciguat in PH patients (N=38) led to sustained, clinically meaningful mean-max reductions in PVR of up to ~38%, one of the highest reductions seen in PH trials to date. Mosliciguat was generally well-tolerated, with low rates of treatment-emergent adverse events (TEAEs).

  Pulmovant initiated the global Phase 2 PHocus trial of mosliciguat in patients with PH-ILD.

- **Roivant:** In October 2024, Roivant reported the close of Organon's acquisition of Dermavant. At closing, Roivant received $184M in cash and Organon took on all of Dermavant's remaining outstanding long-term debt, which, inclusive of Dermavant's senior credit facility repaid at closing, had a carrying value of $336M as of September 30, 2024. In addition, Organon will pay Roivant a $75M milestone upon FDA approval for VTAMA in atopic dermatitis, with a target action date in the first quarter of calendar year 2025. The transaction also includes payments of up to $950 million for the achievements of certain commercial milestones, in addition to the tiered royalties on net sales that Organon will pay Dermavant shareholders.

Roivant continued to return capital through share repurchases with $106M purchased for the quarter ending September 30, 2024, resulting in $754M cumulative share repurchases (inclusive of the repurchase of Sumitomo's stake in April 2024) through September 30, 2024.

Roivant reported consolidated cash, cash equivalents and marketable securities of approximately $5.4B at September 30, 2024.

Major Upcoming Milestones

- **Kinevant** plans to report topline data from the ongoing Phase 2 trial of namilumab for the treatment of sarcoidosis in the fourth quarter of calendar year 2024.
- **Immunovant** plans to have initiated 4-5 potentially registrational programs by March 31, 2025, and plans to have initiated studies in a total of 10 indications by March 31, 2026, for IMVT-1402. In pursuit of this goal, Immunovant now has active INDs in Graves' Disease and difficult-to-treat rheumatoid arthritis and expects to initiate potentially registrational trials in these indications by December 31, 2024 and March 31, 2025 respectively. Topline data from the batoclimab trial in MG is expected by March 31, 2025. Results from this trial are expected to inform a decision regarding next steps for batoclimab in MG and the design of the MG program for IMVT-1402, which is expected to initiate by March 31, 2025. Data from the batoclimab trial in CIDP is expected by March 31, 2025 and will be used to inform the trial design for a potentially registrational program for IMVT-1402. Topline data from the current pivotal program evaluating batoclimab in thyroid eye disease (TED) now expected in the second half of calendar year 2025.
- **Priovant** plans to report topline data from the ongoing Phase 3 trial of brepocitinib in DM in the second half of calendar year 2025.
- **Genevant** Markman hearing in Pfizer / BioNTech action scheduled for December 2024. Summary judgment phase of Moderna action scheduled for second and third quarter of calendar year 2025; Moderna trial scheduled for September 2025.

Second Quarter Ended September 30, 2024 Financial Summary

Cash and Marketable Securities

As of September 30, 2024, the Company had consolidated cash, cash equivalents, restricted cash and marketable securities of approximately $5.4 billion.

Research and Development Expenses

Research and development (R&D) expenses increased by $28.3 million to $143.1 million for the three months ended September 30, 2024, compared to $114.8 million for the three months ended September 30, 2023. This increase was primarily driven by increases in program-specific costs of $19.2 million, personnel-related expenses of $7.2 million, and share-based compensation of $1.6 million.

Within program-specific costs, the increase of $19.2 million was primarily driven by an increase in expense of $34.2 million related to the anti-FcRn franchise, partially offset by a decrease in expense of $18.6 million related to RVT-3101, which was sold to Roche in December 2023.

Non-GAAP R&D expenses were $132.4 million for the three months ended September 30, 2024, compared to $105.3 million for the three months ended September 30, 2023.

General and Administrative Expenses

General and administrative (G&A) expenses increased by $114.3 million to $202.9 million for the three months ended September 30, 2024, compared to $88.6 million for the three months ended September 30, 2023. This increase was primarily due to an increase in personnel-related expenses of $87.0 million, of which $79.1 million related to the one-time cash retention awards approved in July 2024 for each of Matthew Gline, Chief Executive Officer; Mayukh Sukhatme, President and Chief Investment Officer; and Eric Venker, President and Chief Operating Officer (the "2024 Senior Executive Compensation Program") and $6.6 million related to the special one-time cash retention bonus award granted to employees, following approval in December 2023. The increase was also driven by an increase in share-based compensation expense of $21.7 million, primarily due to the long-term equity incentive awards granted in July 2024 pursuant to the 2024 Senior Executive Compensation Program.

Non-GAAP G&A expenses were $142.3 million for the three months ended September 30, 2024, compared to $49.6 million for the three months ended September 30, 2023.

Loss from continuing operations, net of tax

Loss from continuing operations, net of tax was $236.8 million for the three months ended September 30, 2024, compared to a loss from continuing operations, net of tax of $244.6 million for the three months ended September 30, 2023. On a basic and diluted per common share basis, loss from continuing operation was $0.25 and $0.28, respectively, for the three months ended September 30, 2024 and September 30, 2023. Non-GAAP loss from continuing operations, net of tax was $218.7 million for the three months ended September 30, 2024, compared to $154.8 million for the three months ended September 30, 2023.

ROIVANT SCIENCES LTD.
Selected Balance Sheet Data
(unaudited, in thousands)

	September 30, 2024	March 31, 2024
Cash, cash equivalents and restricted cash	$ 1,969,914	$ 6,506,189
Marketable securities	3,428,021	—
Total assets	6,206,028	7,222,482
Total liabilities	625,986	773,953
Total shareholders' equity	5,580,042	6,448,529
Total liabilities and shareholders' equity	6,206,028	7,222,482

ROIVANT SCIENCES LTD.
Condensed Consolidated Statements of Operations
(unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2024	2023	2024	2023
Revenue, net	$ 4,475	$ 3,648	$ 12,465	$ 8,131
Operating expenses:				
Cost of revenues	234	223	447	1,206
Research and development (includes $9,911 and $8,309 of share-based compensation expense for the three months ended September 30, 2024 and 2023 and $20,443 and $15,726 for the six months ended September 30, 2024 and 2023, respectively)	143,073	114,790	263,580	224,206
Acquired in-process research and development	—	13,950	—	26,450
General and administrative (includes $59,443 and $37,755 of share-based compensation expense for the three months ended September 30, 2024 and 2023 and $96,284 and $76,472 for the six months ended September 30, 2024 and 2023, respectively)	202,881	88,576	302,773	179,858
Total operating expenses	346,188	217,539	566,800	431,720
Gain on sale of Telavant net assets	—	—	110,387	—
Loss from operations	(341,713)	(213,891)	(443,948)	(423,589)
Change in fair value of investments	(48,375)	45,849	(63,601)	53,413
Change in fair value of liability instruments	(635)	11,789	515	51,967
Gain on deconsolidation of subsidiaries	—	(17,354)	—	(17,354)
Interest income	(69,773)	(14,299)	(141,900)	(31,014)
Other expense, net	1,453	1,530	5,061	4,357
Loss from continuing operations before income taxes	(224,383)	(241,406)	(244,023)	(484,958)
Income tax expense	12,458	3,236	24,421	4,911
Loss from continuing operations, net of tax	(236,841)	(244,642)	(268,444)	(489,869)
(Loss) income from discontinued operations, net of tax	(43,083)	(86,476)	46,010	(169,094)
Net loss	(279,924)	(331,118)	(222,434)	(658,963)
Net loss attributable to noncontrolling interests	(49,740)	(26,791)	(87,547)	(62,820)
Net loss attributable to Roivant Sciences Ltd.	$ (230,184)	$ (304,327)	$ (134,887)	$ (596,143)
Amounts attributable to Roivant Sciences Ltd.:				
Loss from continuing operations, net of tax	$ (187,101)	$ (218,226)	$ (181,052)	$ (427,784)
(Loss) income from discontinued operations, net of tax	(43,083)	(86,101)	46,165	(168,359)
Net loss attributable to Roivant Sciences Ltd.	$ (230,184)	$ (304,327)	$ (134,887)	$ (596,143)
Basic and diluted net (loss) income per common share:				
Basic and diluted loss from continuing operations	$ (0.25)	$ (0.28)	$ (0.25)	$ (0.56)
Basic and diluted (loss) income from discontinued operations	$ (0.06)	$ (0.11)	$ 0.06	$ (0.22)
Basic and diluted net loss per common share	$ (0.31)	$ (0.40)	$ (0.18)	$ (0.78)
Weighted average shares outstanding:				
Basic	735,470,796	770,227,849	735,642,721	764,780,630
Diluted	735,470,796	770,227,849	735,642,721	764,780,630

ROIVANT SCIENCES LTD.
Reconciliation of GAAP to Non-GAAP Financial Measures
(unaudited, in thousands)

	Note	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Six Months Ended September 30, 2024	Six Months Ended September 30, 2023
Loss from continuing operations, net of tax		$ (236,841)	$ (244,642)	$ (268,444)	$ (489,869)
Adjustments:					
Research and development:					
Share-based compensation	(1)	9,911	8,309	20,443	15,726
Depreciation and amortization	(2)	724	1,205	1,419	2,694
General and administrative:					
Share-based compensation	(1)	59,443	37,755	96,284	76,472
Depreciation and amortization	(2)	1,094	1,235	2,184	2,485
Gain on sale of Telavant net assets	(3)	—	—	(110,387)	—
Other:					
Change in fair value of investments	(4)	(48,375)	45,849	(63,601)	53,413
Change in fair value of liability instruments	(5)	(635)	11,789	515	51,967
Gain on deconsolidation of subsidiaries	(6)	—	(17,354)	—	(17,354)
Estimated income tax impact from adjustments	(7)	(3,986)	1,100	(4,190)	369
Adjusted loss from continuing operations, net of tax (Non-GAAP)		**$ (218,665)**	**$ (154,754)**	**$ (325,777)**	**$ (304,097)**

	Note	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Six Months Ended September 30, 2024	Six Months Ended September 30, 2023
Research and development expenses		**$ 143,073**	**$ 114,790**	**$ 263,580**	**$ 224,206**
Adjustments:					
Share-based compensation	(1)	9,911	8,309	20,443	15,726
Depreciation and amortization	(2)	724	1,205	1,419	2,694
Adjusted research and development expenses (Non-GAAP)		**$ 132,438**	**$ 105,276**	**$ 241,718**	**$ 205,786**

	Note	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Six Months Ended September 30, 2024	Six Months Ended September 30, 2023
General and administrative expenses		**$ 202,881**	**$ 88,576**	**$ 302,773**	**$ 179,858**
Adjustments:					
Share-based compensation	(1)	59,443	37,755	96,284	76,472
Depreciation and amortization	(2)	1,094	1,235	2,184	2,485
Adjusted general and administrative expenses (Non-GAAP)		**$ 142,344**	**$ 49,586**	**$ 204,305**	**$ 100,901**

Notes to non-GAAP financial measures:

(1) Represents non-cash share-based compensation expense.

(2) Represents non-cash depreciation and amortization expense.

(3) Represents a gain on the sale of Telavant net assets to Roche due to achievement of a one-time milestone in June 2024.

(4) Represents the unrealized (gain) loss on equity investments in unconsolidated entities that are accounted for at fair value with changes in value reported in earnings.

(5) Represents the change in fair value of liability instruments, which is non-cash and primarily includes the unrealized (gain) loss relating to the measurement and recognition of fair value on a recurring basis of certain liabilities.

(6) Represents the one-time gain on deconsolidation of subsidiaries.

(7) Represents the estimated tax effect of the adjustments.

Investor Conference Call Information

Roivant will host a live conference call and webcast at 8:00 a.m. ET on Tuesday, November 12, 2024, to report its financial results for the second quarter ended September 30, 2024, and provide a corporate update.

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 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; mosliciguat, an inhaled sGC activator in development for pulmonary hypertension associated with interstitial lung disease; and namilumab, an anti-GM-CSF monoclonal antibody in development for the treatment of pulmonary sarcoidosis. 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.

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