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): August 8, 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 August 8, 2024, Roivant Sciences Ltd. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 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 August 8, 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: August 8, 2024

Exhibit 99.1

Roivant Reports Financial Results for the First Quarter Ended June 30, 2024, and Provides Business Update

BASEL, Switzerland and LONDON and NEW YORK, August 8, 2024 – Roivant (Nasdaq: ROIV) today reported its financial results for the first quarter ended June 30, 2024, and provided a business update.

- Immunovant completed enrollment in batoclimab pivotal myasthenia gravis (MG) trial; topline results and initiation of a potentially registrational program in MG for IMVT-1402 on track for fiscal year end (March 31, 2025)
- Brepocitinib development in non-infectious uveitis (NIU) is progressing to Phase 3 following a successful end of Phase 2 meeting with the FDA
- Brepocitinib Phase 3 VALOR study enrollment in dermatomyositis (DM) is complete and on track to report topline data in 2H 2025; VALOR is the largest interventional DM trial ever conducted with 241 subjects enrolled across 90 sites on four continents
- VTAMA net product revenue was $18.4M for the first quarter ended June 30, 2024, with over 430,000 prescriptions written by approximately 16,000 unique prescribers since launch
- Roivant reported its consolidated cash, cash equivalents and restricted cash of $5.7B at June 30, 2024, following a $648M share repurchase announced in April 2024, and not including a $110M milestone payment received in August 2024 related to the previously announced sale of Telavant, which closed in December 2023

“This continues to be a year of investing, building, and clinical execution for Roivant. We completed enrollment in a major Phase 3 trial at each of Immunovant and Priovant with the batoclimab trial in MG and the brepocitinib trial in DM, respectively,” said Matt Gline, CEO of Roivant. “We are entering a dense period of meaningful clinical data in the coming months, particularly for our anti-FcRN franchise. We are also continuing to evaluate a number of promising additions to our pipeline, and we look forward to unveiling one such program next month.”

Recent Developments

- **Immunovant:** In August 2024, Immunovant announced completion of enrollment in batoclimab pivotal MG trial.

- **Priovant:** In June 2024, Priovant completed an end of Phase 2 meeting with the FDA and will progress brepocitinib to a Phase 3 program in NIU; detailed trial design will be shared at a later date.

  In July 2024, Priovant announced completion of enrollment in VALOR, a global Phase 3 study of brepocitinib in DM. The study enrolled 241 subjects across 90 sites on four continents, making it the largest interventional DM trial ever conducted.

- **Dermavant:** For the first quarter ended June 30, 2024, Roivant reported VTAMA net product revenue of $18.4M. As of July 2024, over 430,000 VTAMA prescriptions have been written by approximately 16,000 unique prescribers for psoriasis. VTAMA is covered for over 141M US commercial lives, including coverage by all three of the top pharmacy benefit managers.

- **Genevant:** In August 2024, the parties requested an amended case schedule in Genevant's and Arbutus's lawsuit against Moderna in order for Moderna to accommodate certain outstanding discovery requests. If the Court approves the request, the trial will begin in September 2025.

- **Roivant:** Roivant reported its consolidated cash, cash equivalents and restricted cash of $5.7B at June 30, 2024, following a $648M share repurchase announced in April 2024, and not including a $110M milestone payment received in August 2024 related to the previously announced sale of Telavant, which closed in December 2023.

Major Upcoming Milestones

- **Dermavant** expects PDUFA action for VTAMA in atopic dermatitis in the fourth quarter of calendar year 2024.

- **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.

- **Priovant** plans to report topline data from the ongoing Phase 3 trial of brepocitinib in DM in the second half of calendar year 2025 and to initiate a Phase 3 program for brepocitinib in NIU in the second half 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 expects to have at least 3 IND applications active by the end of calendar year 2024. Detailed results from the batoclimab study in Graves' disease (GD) and an overview of the development plan for IMVT-1402 in GD are expected in the fall of 2024. Batoclimab topline data in MG are expected to be reported by March 31, 2025. Results from this trial are expected to inform a decision regarding next steps for batoclimab in MG. Immunovant also expects to initiate a potentially registrational program in MG for IMVT-1402 by March 31, 2025. Initial data from period 1 of the batoclimab chronic inflammatory demyelinating polyneuropathy (CIDP) trial and the trial design for IMVT-1402 in CIDP are both expected to be disclosed by March 31, 2025. Topline data from the current pivotal program evaluating batoclimab in thyroid eye disease (TED) continue to be expected in the first half of calendar year 2025.

First Quarter Ended June 30, 2024 Financial Summary

Cash Position

As of June 30, 2024, the Company had consolidated cash, cash equivalents and restricted cash of approximately $5.7 billion.

Research and Development Expenses

Research and development (R&D) expenses increased by $8.1 million to $133.2 million for the three months ended June 30, 2024, compared to $125.1 million for the three months ended June 30, 2023. This increase was primarily driven by increases in program-specific costs of $4.3 million, share-based compensation of $3.1 million, and personnel-related expenses of $1.6 million.

Within program-specific costs, the increase of $4.3 million was primarily driven by an increase in expense of $14.8 million related to the anti-FcRn franchise, partially offset by a decrease in expense of $10.9 million related to RVT-3101 for which the rights to further develop and manufacture were sold to Roche in December 2023.

Non-GAAP R&D expenses were $121.5 million for the three months ended June 30, 2024, compared to $115.7 million for the three months ended June 30, 2023.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses decreased by $7.7 million to $148.5 million for the three months ended June 30, 2024, compared to $156.2 million for the three months ended June 30, 2023, primarily due to a decrease in selling, general and administrative expenses of $16.1 million at Dermavant, which largely resulted from reduced marketing spend. This decrease was partially offset by an increase in personnel-related expenses of $7.3 million, primarily as a result of a special one-time cash retention bonus award granted to employees, following approval in December 2023.

Non-GAAP SG&A expenses were $107.5 million for the three months ended June 30, 2024, compared to $113.0 million for the three months ended June 30, 2023.

Net Income (Loss)

Net income was $57.5 million for the three months ended June 30, 2024, compared to a net loss of $327.8 million for the three months ended June 30, 2023. On a basic and diluted per common share basis, net income was $0.13 and $0.12, respectively, for the three months ended June 30, 2024. Basic and diluted net loss per common share was $0.38 for the three months ended June 30, 2023. Non-GAAP net loss was $131.2 million for the three months ended June 30, 2024, compared to $211.5 million for the three months ended June 30, 2023.

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Selected Balance Sheet Data

(unaudited, in thousands)

	June 30, 2024	March 31, 2024
Cash, cash equivalents and restricted cash	$ 5,693,300	$ 6,550,450
Total assets	6,496,448	7,222,482
Total liabilities	601,162	773,953
Total shareholders' equity	5,895,286	6,448,529
Total liabilities and shareholders' equity	6,496,448	7,222,482

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Condensed Consolidated Statements of Operations

(unaudited, in thousands, except share and per share amounts)

	Three Months Ended June 30,	
	2024	**2023**
Revenues:		
Product revenue, net	$ 18,367	$ 16,659
License, milestone and other revenue	36,765	4,965
Revenue, net	55,132	21,624
Operating expenses:		
Cost of revenues	3,978	4,214
Research and development (includes $11,009 and $7,953 of share-based compensation expense for the three months ended June 30, 2024 and 2023, respectively)	133,208	125,133
Acquired in-process research and development	—	12,500
Selling, general and administrative (includes $39,144 and $41,192 of share-based compensation expense for the three months ended June 30, 2024 and 2023, respectively)	148,519	156,190
Total operating expenses	285,705	298,037
Gain on sale of Telavant net assets	110,387	—
Loss from operations	(120,186)	(276,413)
Change in fair value of investments	(15,226)	7,564
Change in fair value of debt and liability instruments	(118,202)	54,512
Interest income	(72,127)	(16,715)
Interest expense	13,399	8,912
Other expense (income), net	1,825	(4,593)
Income (loss) before income taxes	70,145	(326,093)
Income tax expense	12,655	1,752
Net income (loss)	57,490	(327,845)
Net loss attributable to noncontrolling interests	(37,807)	(36,029)
Net income (loss) attributable to Roivant Sciences Ltd.	$ 95,297	$ (291,816)
Net income (loss) per common share:		
Basic	$ 0.13	$ (0.38)
Diluted	$ 0.12	$ (0.38)
Weighted average shares outstanding:		
Basic	735,816,536	759,273,550
Diluted	781,627,601	759,273,550

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Reconciliation of GAAP to Non-GAAP Financial Measures
(unaudited, in thousands)

	Note	Three Months Ended June 30, 2024	2023
Net income (loss)		**$ 57,490**	**$ (327,845)**
Adjustments:			
Cost of revenues:			
Amortization of intangible assets	(1)	2,350	2,370
Share-based compensation	(2)	38	38
Research and development:			
Share-based compensation	(2)	11,009	7,953
Depreciation and amortization	(3)	694	1,489
Selling, general and administrative:			
Share-based compensation	(2)	39,144	41,192
Depreciation and amortization	(3)	1,839	1,980
Gain on sale of Telavant net assets	(4)	(110,387)	—
Other:			
Change in fair value of investments	(5)	(15,226)	7,564
Change in fair value of debt and liability instruments	(6)	(118,202)	54,512
Estimated income tax impact from adjustments	(7)	12	(732)
Adjusted net loss (Non-GAAP)		**$ (131,239)**	**$ (211,479)**

	Note	Three Months Ended June 30, 2024	2023
Research and development expenses		**$ 133,208**	**$ 125,133**
Adjustments:			
Share-based compensation	(2)	11,009	7,953
Depreciation and amortization	(3)	694	1,489
Adjusted research and development expenses (Non-GAAP)		**$ 121,505**	**$ 115,691**

	Note	Three Months Ended June 30, 2024	2023
Selling, general and administrative expenses		**$ 148,519**	**$ 156,190**
Adjustments:			
Share-based compensation	(2)	39,144	41,192
Depreciation and amortization	(3)	1,839	1,980
Adjusted selling, general and administrative expenses (Non-GAAP)		**$ 107,536**	**$ 113,018**

Notes to non-GAAP financial measures:

(1) Represents non-cash amortization of intangible assets associated with milestone payments made in connection with regulatory approvals.

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

(3) Represents non-cash depreciation and amortization expense, other than amortization of intangible assets associated with milestone payments made in connection with regulatory approvals.

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

(5) 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.

(6) Represents the change in fair value of debt and 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.

(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 Thursday, August 8, 2024, to report its financial results for the first quarter ended June 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 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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