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): February 13, 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 February 13, 2024, Roivant Sciences Ltd. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended December 31, 2023. 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 February 13, 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: February 13, 2024

Exhibit 99.1

Roivant Reports Financial Results for the Third Quarter Ended December 31, 2023, and Provides Business Update

BASEL, LONDON, and NEW YORK, February 13, 2024 – Roivant (Nasdaq: ROIV) today reported its financial results for the third quarter ended December 31, 2023, and provided a business update.

- Roivant completed the sale of Telavant to Roche for $7.1B with an additional $150M in cash payable upon the completion of a near-term milestone
- Batoclimab produced positive results in Graves' disease with response rates meaningfully exceeding 50% in the initial cohort of an ongoing 24-week Phase 2 trial
- VTAMA® (tapinarof) cream, 1% net product revenue was $20.7M for the quarter ended December 31, 2023, with over 300,000 prescriptions written by approximately 14,000 unique prescribers since launch
- New VTAMA positive long-term efficacy and safety data announced from analyses of the ADORING Phase 3 program in atopic dermatitis. Data from these analyses will be included in sNDA submission expected this quarter
- Brepocitinib topline data from the Phase 2 trial in patients with non-infectious uveitis (NIU) is expected this quarter
- Roivant reported its consolidated cash, cash equivalents and restricted cash of $6.7B at December 31, 2023, supporting cash runway into profitability

"This was another productive quarter across the company - we were pleased to announce the closing of the Telavant transaction with Roche in December. I am proud of our continued progress in clinical development, with another positive result generated by the Immunovant team in Graves' disease. The positive initial data continues to support our view of the broad applicability of FcRn and the potentially meaningful clinical benefits associated with deeper IgG suppression," said Matt Gline, CEO of Roivant. "Looking ahead, we are excited about multiple upcoming clinical data readouts and other catalysts expected this year, as well as the prospect of expanding our clinical pipeline. 2024 will be a year of growth for Roivant."

Recent Developments

- **Roivant:** In December 2023, Roivant announced the completion of the sale of Telavant to Roche for an upfront payment of approximately $7.1 billion with an additional $150 million in cash payable upon the completion of a near-term milestone. Under the terms of the agreement, Roche gained the rights to develop, manufacture and commercialize RVT-3101 in the US and Japan for the treatment of inflammatory bowel disease and potentially other diseases. Prior to the closing of the transaction, Roivant owned 75% of the issued and outstanding shares of common stock and preferred stock of Telavant and Pfizer owned the remaining 25%, in each case on an as-converted basis. Roivant's net cash proceeds from the transaction are approximately $5.2 billion. Approximately $110 million of the additional milestone payment will be payable to Roivant.

Roivant reported its consolidated cash, cash equivalents and restricted cash of $6.7 billion at December 31, 2023.

- **Immunovant:** In November 2023, Immunovant reported IMVT-1402, a second-generation antibody targeting the neonatal fragment crystallizable receptor (FcRn), continued to show potentially best-in-class profile in a Phase 1 clinical trial in healthy adults. Initial data from the 600 mg MAD cohort showed that four subcutaneously administered doses of 600 mg IMVT-1402 reduced total immunoglobulin G (IgG) levels by a mean of 74%, very similar to the 76% IgG reduction after four weekly injections of 680 mg batoclimab, but with no or minimal changes in serum albumin and LDL cholesterol, consistent with observations in placebo.

  In December 2023, Immunovant reported in an open-label Phase 2 proof-of-concept clinical trial of batoclimab in Graves' disease, response rates from an initial cohort of patients who were hyperthyroid despite treatment with an anti-thyroid medication for more than 12 weeks were meaningfully higher than 50 percent, after receiving once-weekly subcutaneous injections of 680 mg batoclimab for 12 weeks. This trial is ongoing.

- **Dermavant:** For the third quarter ended December 31, 2023, Roivant reported VTAMA net product revenue of $20.7M, representing a 28.5% gross-to-net yield for the quarter. As of February 2024, over 300,000 VTAMA prescriptions[1] have been written by approximately 14,000 unique prescribers for psoriasis[2], based on IQVIA data. VTAMA is covered for 137 million US commercial lives, including coverage by all three of the top pharmacy benefit managers.

  In January 2024, Dermavant announced new positive efficacy and safety data from analyses of ADORING 3, an ongoing open-label, long-term extension Phase 3 trial being conducted to evaluate the safety and efficacy of VTAMA cream, 1% in patients with AD for up to 48 weeks of total treatment. The integrated analysis across the ADORING development program showed that efficacy continued to improve beyond the 8-week double blind treatment period in ADORING 1 and ADORING 2 across multiple endpoints including:

  - vIGA-AD score of 0 (clear) or 1 (almost clear) with at least a 2-grade improvement from baseline was observed in 73% (519/711) of patients included
  - 80.7% (574/711) of patients achieved at least a 75% improvement in the Eczema Area and Severity Index (EASI75)
  - 77.9% (218/280) of patients ≥12 years old with a baseline Peak Pruritus Numeric Rating Scale (PP-NRS) score ≥4 achieved a ≥4-point reduction in PP-NRS
  - 92.3% (656/711) of patients achieved at least a 1-grade improvement in vIGA-AD score

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[1] IQVIA National Prescription Audit (NPA) for the 3-month period ending 1/26/2024, reflecting estimates of real-world activity. All rights reserved.
[2] NPA for the period 5/20/22 to 1/19/2024, reflecting estimates of real-world activity. All rights reserved.

The interim analysis of the ADORING 3 open-label, long-term extension Phase 3 trial demonstrated that 51.2% (373/728) of patients achieved complete disease clearance (vIGA-AD score of 0). No new safety signals were observed with up to 56 weeks of treatment. Data from these analyses will be included in sNDA submission expected this quarter.

- **Hemavant:** We have discontinued the development of RVT-2001 after an interim data analysis from the Phase 1/2 study.

Major Upcoming Milestones

- **Immunovant** expects initial results from period 1 of the Phase 2b clinical trial of batoclimab in CIDP in the second or third quarter of calendar year 2024, while top-line data from the Phase 3 clinical trials of batoclimab in MG and TED are on track and expected in the second half of calendar year 2024 and the first half of calendar year 2025, respectively. For IMVT-1402, Immunovant plans to initiate 4-5 potentially registrational programs by March 31, 2025 and plans to initiate trials in 10 indications by March 31, 2026 (inclusive of the 4-5 potentially registrational programs).

- **Priovant** expects to announce topline results from the Phase 2 POC study in non-infectious uveitis (NIU) in the first quarter of calendar year 2024 and topline results from the Phase 3 trial in dermatomyositis (DM) in calendar year 2025.

- **Dermavant** plans to submit its sNDA for VTAMA in atopic dermatitis to the FDA in the first 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 second half of calendar year 2024.

Third Quarter Ended December 31, 2023 Financial Summary

Cash Position

As of December 31, 2023, the Company had consolidated cash, cash equivalents and restricted cash of $6.7 billion.

Research and Development Expenses

Research and development expenses decreased by $1.8 million to $123.7 million for the three months ended December 31, 2023, compared to $125.5 million for the three months ended December 31, 2022. Changes in the components of research and development expenses included a decrease in program-specific costs of $10.0 million offset by increases in personnel-related expenses of $6.5 million and other expenses of $1.1 million.

Within program-specific costs, the decrease of $10.0 million was primarily driven by a decrease of $9.5 million related to other development and discovery programs due to the deconsolidation of Proteovant Sciences, Inc. ("Proteovant") in August 2023, along with the reprioritization of certain programs and drug discovery efforts, and decreases of $3.1 million each related to RVT-2001 and batoclimab. These decreases were partially offset by an increase in expense of $4.0 million related to RVT-3101, which was acquired in November 2022, and an increase of $3.5 million related to IMVT-1402. The rights to further develop and manufacture RVT-3101 were sold to Roche in December 2023.

The increase of $6.5 million in personnel-related expenses was primarily driven by a special one-time cash retention bonus award granted to employees during the three months ended December 31, 2023.

Non-GAAP R&D expenses were $115.2 million for the three months ended December 31, 2023, compared to $117.4 million for the three months ended December 31, 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $29.0 million to $197.3 million for the three months ended December 31, 2023, compared to $168.3 million for the three months ended December 31, 2022, primarily due to an increase in personnel-related expenses of $27.0 million as a result of a special one-time cash retention bonus award granted to employees.

Non-GAAP SG&A expenses were $148.4 million for the three months ended December 31, 2023, compared to $115.9 million for the three months ended December 31, 2022.

Gain on Sale of Telavant Net Assets

Gain on sale of Telavant net assets resulted from the sale of our entire equity interest in Telavant to Roche in December 2023. At closing, we received approximately $5.2 billion in cash for our pro rata portion of the consideration. Additionally, we derecognized the carrying amount of noncontrolling interest in Telavant of $87.5 million and transferred net liabilities of $26.5 million. This resulted in a gain of approximately $5.3 billion.

Net Income (Loss)

Net income was approximately $5.1 billion for the three months ended December 31, 2023, compared to a net loss of $384.9 million for the three months ended December 31, 2022. On a basic and diluted per common share basis, net income was $6.37 and $6.03, respectively, for the three months ended December 31, 2023. Basic and diluted net loss per common share was $0.49 for the three months ended December 31, 2022. Non-GAAP net loss was $174.9 million for the three months ended December 31, 2023, compared to $297.5 million for the three months ended December 31, 2022.

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Selected Balance Sheet Data

(unaudited, in thousands)

	December 31, 2023	March 31, 2023
Cash, cash equivalents and restricted cash	$ 6,685,458	$ 1,692,115
Total assets	7,312,679	2,389,604
Total liabilities	728,097	782,017
Total shareholders' equity	6,584,582	1,607,587
Total liabilities and shareholders' equity	7,312,679	2,389,604

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Condensed Consolidated Statements of Operations

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

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2023	2022	2023	2022
Revenues:				
Product revenue, net	$ 20,666	$ 9,244	$ 55,749	$ 14,354
License, milestone and other revenue	16,474	7,808	40,116	19,550
Revenue, net	37,140	17,052	95,865	33,904
Operating expenses:				
Cost of revenues	3,668	3,586	11,148	8,953
Research and development (includes $7,475 and $6,888 of share-based compensation expense for the three months ended December 31, 2023 and 2022 and $24,305 and $26,548 for the nine months ended December 31, 2023 and 2022, respectively)	123,717	125,533	380,834	393,358
Acquired in-process research and development	—	97,749	26,450	97,749
Selling, general and administrative (includes $46,944 and $50,741 of share-based compensation expense for the three months ended December 31, 2023 and 2022 and $128,445 and $165,771 for the nine months ended December 31, 2023 and 2022, respectively)	197,282	168,261	517,827	474,996
Total operating expenses	324,667	395,129	936,259	975,056
Gain on sale of Telavant net assets	5,348,410	—	5,348,410	—
Income (loss) from operations	5,060,883	(378,077)	4,508,016	(941,152)
Change in fair value of investments	10,467	(25,948)	63,880	53,277
Change in fair value of debt and liability instruments	9,331	62,360	85,376	90,032
Gain on deconsolidation of subsidiaries	—	(12,514)	(17,354)	(29,276)
Interest income	(31,953)	(10,249)	(62,967)	(17,900)
Interest expense	9,444	8,446	27,603	19,393
Other income, net	(34,743)	(18,095)	(33,405)	(11,060)
Net income (loss) before income taxes	5,098,337	(382,077)	4,444,883	(1,045,618)
Income tax expense	25,672	2,819	31,181	8,983
Net income (loss)	5,072,665	(384,896)	4,413,702	(1,054,601)
Net loss attributable to noncontrolling interests	(23,519)	(32,882)	(86,339)	(79,188)
Net income (loss) attributable to Roivant Sciences Ltd.	$ 5,096,184	$ (352,014)	$ 4,500,041	$ (975,413)
Net income (loss) per common share:				
Basic	$ 6.37	$ (0.49)	$ 5.79	$ (1.39)
Diluted	$ 6.03	$ (0.49)	$ 5.46	$ (1.39)
Weighted average shares outstanding:				
Basic	800,587,716	713,319,399	776,759,728	703,054,773
Diluted	844,461,685	713,319,399	824,310,013	703,054,773

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Reconciliation of GAAP to Non-GAAP Financial Measures

(unaudited, in thousands)

	Note	Three Months Ended December 31,		Nine Months Ended December 31,	
		2023	2022	2023	2022
Net income (loss)		**$ 5,072,665**	**$ (384,896)**	**$ 4,413,702**	**$ (1,054,601)**
Adjustments:					
Cost of revenues					
Amortization of intangible assets	(1)	2,442	2,228	7,211	5,170
Share-based compensation	(2)	55	—	153	—
Research and development:					
Share-based compensation	(2)	7,475	6,888	24,305	26,548
Depreciation and amortization	(3)	1,023	1,258	3,717	3,558
Selling, general and administrative:					
Share-based compensation	(2)	46,944	50,741	128,445	165,771
Depreciation and amortization	(3)	1,956	1,664	5,902	4,176
Gain on sale of Telavant net assets	(4)	(5,348,410)	—	(5,348,410)	—
Other:					
Change in fair value of investments	(5)	10,467	(25,948)	63,880	53,277
Change in fair value of debt and liability instruments	(6)	9,331	62,360	85,376	90,032
Gain on deconsolidation of subsidiaries	(7)	—	(12,514)	(17,354)	(29,276)
Estimated income tax impact from adjustments	(8)	21,199	756	21,351	410
Adjusted net loss (Non-GAAP)		**$ (174,853)**	**$ (297,463)**	**$ (611,722)**	**$ (734,935)**

	Note	Three Months Ended December 31, 2023	Three Months Ended December 31, 2022	Nine Months Ended December 31, 2023	Nine Months Ended December 31, 2022
Research and development expenses		**$ 123,717**	**$ 125,533**	**$ 380,834**	**$ 393,358**
Adjustments:					
Share-based compensation	(2)	7,475	6,888	24,305	26,548
Depreciation and amortization	(3)	1,023	1,258	3,717	3,558
Adjusted research and development expenses (Non-GAAP)		**$ 115,219**	**$ 117,387**	**$ 352,812**	**$ 363,252**

	Note	Three Months Ended December 31, 2023	Three Months Ended December 31, 2022	Nine Months Ended December 31, 2023	Nine Months Ended December 31, 2022
Selling, general and administrative expenses		**$ 197,282**	**$ 168,261**	**$ 517,827**	**$ 474,996**
Adjustments:					
Share-based compensation	(2)	46,944	50,741	128,445	165,771
Depreciation and amortization	(3)	1,956	1,664	5,902	4,176
Adjusted selling, general and administrative expenses (Non-GAAP)		**$ 148,382**	**$ 115,856**	**$ 383,480**	**$ 305,049**

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 one-time gain on the sale of Telavant net assets to Roche in December 2023.

(5) Represents the unrealized 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 loss relating to the measurement and recognition of fair value on a recurring basis of certain liabilities.

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

(8) 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, February 13, 2024, to report its financial results for the third quarter ended December 31, 2023, 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; batoclimab and IMVT-1402, fully human monoclonal antibodies targeting the neonatal Fc receptor ("FcRn") in development across several IgG-mediated autoimmune indications; brepocitinib, a novel TYK2/JAK1 inhibitor in late stage development for dermatomyositis and other autoimmune conditions, 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," "suggest," "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 products and product candidates, plans to develop our product candidates for particular indications, the availability and success of topline results from our ongoing clinical trials, cash runway and profitability 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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