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 13, 2023

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 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 13, 2023, Roivant Sciences Ltd. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 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 November 13, 2023
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 13, 2023

Exhibit 99.1

Roivant Reports Financial Results for the Second Quarter Ended September 30, 2023, and Provides Business Update

- Roivant entered into a definitive agreement with Roche for the sale of Telavant for $7.1B upfront and a milestone payment of $150M payable upon the initiation of a Phase 3 trial in ulcerative colitis
- IMVT-1402 subcutaneous (SC) doses achieved peak Immunoglobulin G (IgG) reductions that are similar to those previously observed with batoclimab, based on initial results from Phase 1 single-ascending dose and 300 mg multiple-ascending dose studies
- IMVT-1402 showed no statistically significant dose-related decrease in serum albumin below baseline or increase in low-density lipoprotein cholesterol (LDL-C) above baseline after 4 weeks of dosing in the 300 mg multiple-ascending dose (MAD) SC cohort
- VTAMA® (tapinarof) cream, 1% net product revenue was $18.4M for the quarter ended September 30, 2023, with over 250,000 prescriptions written by approximately 12,800 unique prescribers since launch
- Roivant reported cash, cash equivalents and restricted cash of approximately $1.4B at September 30, 2023. Giving effect to Immunovant's October 2023 follow-on offering and expected cash proceeds from the pending sale of Telavant (including one-time milestone), Roivant's cash, cash equivalents and restricted cash would have been approximately $7.0B
- Roivant appointed President and Chief Investment Officer, Mayukh Sukhatme, M.D., to its Board of Directors

BASEL, LONDON, and NEW YORK, November 13, 2023 – Roivant (Nasdaq: ROIV) today reported its financial results for the second quarter ended September 30, 2023, and provided an update on the business.

"In the last few weeks, we announced a historic deal with Roche for the sale of Telavant for $7.25 billion. While we intend to be very thoughtful about capital deployment, we expect that the resulting cash will be sufficient to fund our programs through profitability, in addition to enabling other opportunities and investments," said Matt Gline, CEO of Roivant. "This was also another significant quarter for our clinical programs with a data readout from IMVT-1402's Phase 1 SAD study and 300 mg MAD cohort. The data represent what we believe is the best-case scenario for our FcRn franchise and truly broadens the horizon for what is possible in the landscape of autoimmune therapies and for patients suffering from autoimmune diseases. We are excited about the recent progress and look forward to announcing additional clinical results for 1402 and brepocitinib in the final quarter of the calendar year. 2023 has continued to deliver on being an incredibly catalyst-rich year, and certainly Roivant's biggest year yet."

Recent Developments

- **Telavant:** In October 2023, Roivant entered into a definitive agreement with Roche for the sale of Telavant. Roche will gain 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. Under the terms of the agreement, Roche will pay a purchase price of $7.1 billion upfront and a milestone payment of $150 million payable upon the initiation of a Phase 3 trial in ulcerative colitis. Roivant owns 75% of the issued and outstanding shares of common stock and preferred stock of Telavant and Pfizer owns the remaining 25%, in each case on an as-converted basis. Roivant's net proceeds from the transaction are expected to be approximately $5.2 billion plus $110 million from the milestone payment. Regulatory filings in connection with the transaction have been submitted and the closing of the transaction remains on track for the fourth quarter of 2023 or the first quarter of 2024.

- **Immunovant:** In September 2023, Immunovant announced initial data from the Phase 1 clinical trial evaluating the safety, tolerability, and pharmacodynamic profiles of IMVT-1402 in healthy adults showed that subcutaneously administered doses of IMVT-1402 produced dose-dependent reductions in Immunoglobulin G, with no statistically significant dose-related decrease in serum albumin or increase in LDL cholesterol, strengthening IMVT-1402 as a potential best-in-class neonatal fragment crystallizable receptor (FcRn) inhibitor. In October 2023, Immunovant announced the closing of an underwritten public offering and concurrent private placement offering of common stock yielding approximately $467 million in net proceeds to Immunovant, after deducting underwriting commissions and estimated offering expenses. Roivant owns approximately 55.2% of Immunovant as of November 3, 2023.

- **Dermavant:** For the second quarter ended September 30, 2023, Roivant reported VTAMA net product revenue of $18.4M, representing a 28% gross-to-net yield for the quarter. As of November 2023, over 250,000 VTAMA prescriptions have been written by approximately 12,800 unique prescribers for psoriasis, based on IQVIA data. Coverage has been expanded to 137 million US commercial lives and includes coverage by all three of the top pharmacy benefit managers.

  In October 2023, Dermavant reported that in adult patients, VTAMA showed positive results from a Phase 4 open-label trial for the treatment of intertriginous plaque psoriasis - 82.8% achieved an intertriginous Physician Global Assessment (iPGA) Score of 0 (clear) or 1 (almost clear) and ≥2-grade improvement from baseline at Week 12, demonstrating compelling efficacy. Additionally, Dermavant reported in adults and children down to two years of age with atopic dermatitis, VTAMA showed rapid and significant onset of pruritus (itch) relief as early as 24 hours after initial application.

- **Roivant:** In September 2023, Roivant raised approximately $200 million in a follow-on offering. Roivant reported cash, cash equivalents and restricted cash of approximately $1.4 billion at September 30, 2023. Giving effect to Immunovant's October 2023 follow-on offering and expected cash proceeds from the pending sale of Telavant (including one-time milestone), Roivant's cash, cash equivalents and restricted cash would have been approximately $7.0 billion. The acquisition of Telavant is subject to customary closing conditions and is expected to close in the fourth quarter of 2023 or the first quarter of 2024.

Major Upcoming Milestones

- **Immunovant** expects additional IMVT-1402 data from the 600 mg multiple-ascending dose cohort in November 2023. Additionally, for batoclimab: Top-line data from the Phase 3 clinical trial in MG are expected in the second half of calendar year 2024. For the Phase 3 program in TED, top-line data are expected in the first half of calendar year 2025. Immunovant also expects to have initial results from period 1 of the Phase 2B clinical trial in CIDP in the first half of calendar year 2024, and initial Phase 2 proof-of-concept data in Graves' disease by the end of calendar year 2023.

- **Priovant** plans to announce topline results from the potentially registrational trial evaluating brepocitinib for the treatment of patients with systemic lupus erythematosus (SLE) in the fourth quarter of calendar year 2023. Priovant also 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.

- **Hemavant** plans to announce data from the ongoing open-label Phase 1/2 trial evaluating RVT-2001 for the treatment of transfusion-dependent anemia in lower-risk myelodysplastic syndromes (MDS) patients 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.

Second Quarter Ended September 30, 2023 Financial Summary

Cash Position

As of September 30, 2023, the Company had consolidated cash, cash equivalents and restricted cash of $1.4 billion.

Research and Development Expenses

Research and development expenses were $132.0 million for each of the three months ended September 30, 2023, and 2022. Changes in the components of research and development expenses included a decrease in personnel-related expenses of $5.4 million and increases in share-based compensation expense of $1.5 million and program-specific costs of $1.2 million.

Within program-specific costs, the primary drivers of change during the three months ended September 30, 2023 as compared to the three months ended September 30, 2022 were an additional expense of $18.6 million related to RVT-3101, which was acquired in November 2022, and a decrease in expenses related to other development and discovery programs of $18.2 million, which in part resulted from the deconsolidation of Proteovant in August 2023 along with the reprioritization of certain programs and drug discovery efforts.

Non-GAAP R&D expenses were $121.9 million for the three months ended September 30, 2023, compared to $123.3 million for the three months ended September 30, 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $6.7 million to $164.4 million for the three months ended September 30, 2023, compared to $157.7 million for the three months ended September 30, 2022, primarily due to an increase in selling, general and administrative expenses of $21.8 million at Dermavant as a result of the progression of the commercial launch of VTAMA, partially offset by a decrease of $14.2 million of share-based compensation expense.

Non-GAAP SG&A expenses were $122.1 million for the three months ended September 30, 2023, compared to $101.5 million for the three months ended September 30, 2022. The majority of non-GAAP SG&A expenses were related to Dermavant's SG&A and ongoing VTAMA commercial launch activities.

Net Loss

Net loss was $331.1 million for the three months ended September 30, 2023, compared to $315.9 million for the three months ended September 30, 2022. On a per common share basis, net loss was $0.40 for the three months ended September 30, 2023, and $0.42 for the three months ended September 30, 2022. Non-GAAP net loss was $225.4 million for the three months ended September 30, 2023, compared to $226.8 million for the three months ended September 30, 2022.

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

	September 30, 2023	March 31, 2023
Cash, cash equivalents and restricted cash	$ 1,423,188	$ 1,692,115
Total assets	2,065,543	2,389,604
Total liabilities	739,910	782,017
Total shareholders' equity	1,325,633	1,607,587
Total liabilities and shareholders' equity	2,065,543	2,389,604

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,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product revenue, net	$ 18,424	$ 4,969	$ 35,083	$ 5,110
License, milestone and other revenue	18,677	7,564	23,642	11,742
Revenue, net	37,101	12,533	58,725	16,852
Operating expenses:				
Cost of revenues	3,266	3,641	7,480	5,367
Research and development (includes $8,877 and $7,417 of share-based compensation expense for the three months ended September 30, 2023 and 2022 and $16,830 and $19,660 for the six months ended September 30, 2023 and 2022, respectively)	131,984	131,995	257,117	267,825
Acquired in-process research and development	13,950	—	26,450	—
Selling, general and administrative (includes $40,309 and $54,479 of share-based compensation expense for the three months ended September 30, 2023 and 2022 and $81,501 and $115,030 for the six months ended September 30, 2023 and 2022, respectively)	164,355	157,663	320,545	306,735
Total operating expenses	313,555	293,299	611,592	579,927
Loss from operations	(276,454)	(280,766)	(552,867)	(563,075)
Change in fair value of investments	45,849	54,678	53,413	79,225
Change in fair value of debt and liability instruments	21,533	(13,541)	76,045	27,672
Gain on deconsolidation of subsidiaries	(17,354)	(16,762)	(17,354)	(16,762)
Interest income	(14,299)	(5,670)	(31,014)	(7,651)
Interest expense	9,247	8,335	18,159	10,947
Other expense, net	5,931	5,950	1,338	7,035
Loss before income taxes	(327,361)	(313,756)	(653,454)	(663,541)
Income tax expense	3,757	2,165	5,509	6,164
Net loss	(331,118)	(315,921)	(658,963)	(669,705)
Net loss attributable to noncontrolling interests	(26,791)	(24,331)	(62,820)	(46,306)
Net loss attributable to Roivant Sciences Ltd.	$ (304,327)	$ (291,590)	$ (596,143)	$ (623,399)
Net loss per common share—basic and diluted	$ (0.40)	$ (0.42)	$ (0.78)	$ (0.89)
Weighted average shares outstanding—basic and diluted	770,227,849	699,888,061	764,780,630	697,894,414

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

	Note	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Six Months Ended September 30, 2023	Six Months Ended September 30, 2022
Net loss		**$ (331,118)**	**$ (315,921)**	**$ (658,963)**	**$ (669,705)**
Adjustments:					
Cost of revenues					
Amortization of intangible assets	(1)	2,399	2,200	4,769	2,942
Share-based compensation	(2)	60	—	98	—
Research and development:					
Share-based compensation	(2)	8,877	7,417	16,830	19,660
Depreciation and amortization	(3)	1,205	1,230	2,694	2,300
Selling, general and administrative:					
Share-based compensation	(2)	40,309	54,479	81,501	115,030
Depreciation and amortization	(3)	1,966	1,646	3,946	2,512
Other:					
Change in fair value of investments	(4)	45,849	54,678	53,413	79,225
Change in fair value of debt and liability instruments	(5)	21,533	(13,541)	76,045	27,672
Gain on deconsolidation of subsidiaries	(6)	(17,354)	(16,762)	(17,354)	(16,762)
Estimated income tax impact from adjustments	(7)	884	(2,219)	152	(346)
Adjusted net loss (Non-GAAP)		**$ (225,390)**	**$ (226,793)**	**$ (436,869)**	**$ (437,472)**

	Note	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Six Months Ended September 30, 2023	Six Months Ended September 30, 2022
Research and development expenses		**$ 131,984**	**$ 131,995**	**$ 257,117**	**$ 267,825**
Adjustments:					
Share-based compensation	(2)	8,877	7,417	16,830	19,660
Depreciation and amortization	(3)	1,205	1,230	2,694	2,300
Adjusted research and development expenses (Non-GAAP)		**$ 121,902**	**$ 123,348**	**$ 237,593**	**$ 245,865**

	Note	Three Months Ended September 30,		Six Months Ended September 30,	
		2023	2022	2023	2022
Selling, general and administrative expenses		**$ 164,355**	**$ 157,663**	**$ 320,545**	**$ 306,735**
Adjustments:					
Share-based compensation	(2)	40,309	54,479	81,501	115,030
Depreciation and amortization	(3)	1,966	1,646	3,946	2,512
Adjusted selling, general and administrative expenses (Non-GAAP)		**$ 122,080**	**$ 101,538**	**$ 235,098**	**$ 189,193**

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 the unrealized 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 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.

(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 Monday, November 13, 2023, to report its financial results for the second quarter ended September 30, 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, systemic lupus erythematosus, and other autoimmune conditions; and, additional 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 the pending sale of our subsidiary Telavant to Roche (the "Telavant Transaction"), 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.

The Telavant Transaction is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary closing conditions. There can be no assurance that the Telavant Transaction will close on the timelines specified in this presentation or at all.

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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