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 14, 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**
Redeemable warrants, each whole warrant exercisable for one Common Share	**ROIVW**	**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 August 14, 2023, Roivant Sciences Ltd. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 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 August 14, 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: August 14, 2023

Exhibit 99.1

Roivant Reports Financial Results for the First Quarter Ended June 30, 2023, and Provides Business Update

- RVT-3101 demonstrated improved efficacy results from the induction to chronic period in the TUSCANY-2 Phase 2b study in ulcerative colitis and was well tolerated with a favorable safety profile across all doses
- First patient has been dosed in the TAHOE study, a global Phase 2 trial of RVT-3101 in Crohn's disease, with topline data from the induction portion expected in the fourth quarter of calendar year 2024
- Initial data from the Phase 1 clinical trial of IMVT-1402 remains on track for September 2023 (single-ascending dose) and October / November 2023 (multiple-ascending dose)
- VTAMA® (tapinarof) net product revenue was $16.7M for the quarter ended June 30, 2023, with nearly 200,000 prescriptions written by approximately 11,500 unique prescribers since launch
- VTAMA® gross-to-net yield was 26% for the quarter ended June 30, 2023, and as of August 2023, coverage has been expanded to 129 million US commercial lives and 87 million government lives
- VTAMA® met the primary and all secondary endpoints in ADORING 1, the second of two replicate Phase 3 studies in patients with moderate-to-severe atopic dermatitis – no new safety or tolerability signals were observed in this population, which included children as young as 2 years old
- Sixth positive Phase 2 study of oral brepocitinib further validates TYK2/JAK1 inhibition activity in highly inflammatory autoimmune diseases
- Roivant reported its consolidated cash, cash equivalents and restricted cash of $1.4B at June 30, 2023, supporting cash runway into the second half of calendar year 2025

BASEL, LONDON, and NEW YORK, August 14, 2023 – Roivant (Nasdaq: ROIV) today reported its financial results for the first quarter ended June 30, 2023, and provided an update on the business.

"This was an incredibly busy quarter with multiple clinical readouts and trial initiations. We reported positive data from the chronic period of the Phase 2b study of RVT-3101 in ulcerative colitis, in addition to positive data from the ADORING 1 trial evaluating VTAMA in patients as young as 2 years old with moderate-to-severe atopic dermatitis. We also initiated two separate trials, the TAHOE Phase 2 study of RVT-3101 in Crohn's disease and the Phase 1 study of IMVT-1402 in healthy volunteers. We're incredibly excited about the progress we've made in this quarter alone and look forward to announcing additional clinical results in the upcoming months," said Matt Gline, CEO of Roivant. "On the commercial side, we saw another three months of continued product revenue growth for the company from VTAMA sales."

Recent Developments

- **Telavant:** In June 2023, Telavant reported positive data from the chronic period of TUSCANY-2, a large, global Phase 2b study evaluating RVT-3101 for the treatment of ulcerative colitis. Outcomes were measured at week 56 for the chronic period (vs. week 14 from the previously reported induction period). At the expected Phase 3 dose in the overall population and in the biomarker positive populations, RVT-3101 treatment produced clinically meaningful efficacy results with improved Clinical Remission, Endoscopic Improvement, and Endoscopic Remission at week 56. In July 2023, Telavant announced the first patient was dosed in the TAHOE study, a global Phase 2 trial of RVT-3101 in patients with moderate to severe Crohn's disease.

- **Immunovant:** In August 2023, Immunovant reported that initial data from the Phase 1 clinical trial of IMVT-1402 remains on track for September 2023 (single-ascending dose) and October / November 2023 (multiple-ascending dose).

- **Dermavant:** For the first quarter ended June 30, 2023, Roivant reported VTAMA net product revenue of $16.7M, representing a 26% gross-to-net yield for the quarter. As of August 2023, nearly 200,000 VTAMA prescriptions have been written by approximately 11,500 unique prescribers for psoriasis, based on IQVIA data. Coverage has been expanded to 129 million US commercial lives and 87 million government lives and includes coverage by all three of the top pharmacy benefit managers. In May 2023, VTAMA met the primary and all secondary endpoints in ADORING 1, the second of two replicate Phase 3 studies in patients with moderate-to-severe atopic dermatitis. Importantly, no new safety or tolerability signals were observed in this population, which included children as young as 2 years old.

- **Priovant:** In August 2023, Priovant announced the sixth positive Phase 2 study of oral brepocitinib, out of six conducted, with statistically significant, positive results from the 12-week induction period of Pfizer's Phase 2 study of brepocitinib in adult patients with moderate to severe Crohn's disease. The primary and key secondary endpoints were met with safety and tolerability generally consistent with prior brepocitinib studies, further validating TYK2/JAK1 inhibition activity in highly inflammatory autoimmune diseases.

- **Roivant:** Roivant reported its consolidated cash, cash equivalents and restricted cash of $1.4B at June 30, 2023, supporting cash runway into the second half of calendar year 2025.

Major Upcoming Milestones

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

- **Immunovant** expects IMVT-1402 Phase 1 initial data from single-ascending dose cohorts in September 2023 and initial data from multiple-ascending dose cohorts in October or November 2023. Additionally, for batoclimab: top-line results from the ongoing myasthenia gravis (MG) trial are expected in the second half of calendar year 2024. Top-line results from the Phase 3 thyroid eye disease (TED) program, consisting of two Phase 3 clinical trials, 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 chronic inflammatory demyelinating polyneuropathy (CIDP) in the first half of calendar year 2024. Initial results from the Phase 2 proof-of-concept trial in Graves' disease (GD) are expected in the fourth quarter of calendar year 2023.

- **Telavant** has initiated a Phase 2 dose-ranging study of RVT-3101 in Crohn's disease with data from the induction portion expected in the fourth quarter of calendar year 2024.

- **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.

- **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 second half of calendar year 2023.

- **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.

First Quarter Ended June 30, 2023, Financial Summary

Cash Position

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

Research and Development Expenses

Research and development (R&D) expenses decreased by $10.7 million to $125.1 million for the three months ended June 30, 2023, compared to $135.8 million for the three months ended June 30, 2022, primarily due to decreases in program-specific costs of $7.8 million and share-based compensation of $4.3 million, partially offset by an increase in other expenses of $2.2 million.

The decrease of $7.8 million in program-specific costs largely reflects the discontinued development of several programs, including ARU-1801, LSVT-1701 and CVT-TCR-01, as well as our reprioritization of drug discovery efforts. These decreases were partially offset by increases reflecting the progression of our programs, including Immunovant's anti-FcRn franchise, RVT-3101, and namilumab. The asset acquisition of RVT-3101 was completed in November 2022.

Non-GAAP R&D expenses were $115.7 million for the three months ended June 30, 2023, compared to $122.5 million for the three months ended June 30, 2022.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development was $12.5 million for the three months ended June 30, 2023, relating to the achievement of development and regulatory milestones for batoclimab.

Selling, General and Administrative Expenses

Selling, general and administrative expenses (SG&A) increased by $7.1 million to $156.2 million for the three months ended June 30, 2023, compared to $149.1 million for the three months ended June 30, 2022, primarily due to a decrease of $19.4 million of share-based compensation expense partially offset by an increase in selling, general and administrative expenses of $27.1 million at Dermavant as a result of the commercial launch of VTAMA.

Non-GAAP SG&A expenses were $113.0 million for the three months ended June 30, 2023, compared to $87.7 million for the three months ended June 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 $327.8 million for the three months ended June 30, 2023, compared to $353.8 million for the three months ended June 30, 2022. On a per common share basis, net loss was $0.38 for the three months ended June 30, 2023, and $0.48 for the three months ended June 30, 2022. Non-GAAP net loss was $211.5 million for the three months ended June 30, 2023, compared to $210.7 million for the three months ended June 30, 2022.

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

	June 30, 2023	March 31, 2023
Cash, cash equivalents and restricted cash	$ 1,449,648	$ 1,692,115
Total assets	2,136,646	2,389,604
Total liabilities	802,507	782,017
Total shareholders' equity	1,334,139	1,607,587
Total liabilities, redeemable noncontrolling interest and shareholders' equity	2,136,646	2,389,604

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

	Three Months Ended June 30,	
	2023	**2022**
Revenues:		
Product revenue, net	$ 16,659	$ 141
License, milestone and other revenue	4,965	4,178
Revenue, net	$ 21,624	$ 4,319
Operating expenses:		
Cost of revenues	4,214	1,726
Research and development (includes $7,953 and $12,243 of share-based compensation expense for the three months ended June 30, 2023 and 2022, respectively)	125,133	135,830
Acquired in-process research and development	12,500	—
Selling, general and administrative (includes $41,192 and $60,551 of share-based compensation expense for the three months ended June 30, 2023 and 2022, respectively)	156,190	149,072
Total operating expenses	298,037	286,628
Loss from operations	(276,413)	(282,309)
Change in fair value of investments	7,564	24,547
Change in fair value of debt and liability instruments	54,512	41,213
Interest income	(16,715)	(1,981)
Interest expense	8,912	2,612
Other (income) expense, net	(4,593)	1,085
Loss before income taxes	(326,093)	(349,785)
Income tax expense	1,752	3,999
Net loss	(327,845)	(353,784)
Net loss attributable to noncontrolling interests	(36,029)	(21,975)
Net loss attributable to Roivant Sciences Ltd.	$ (291,816)	$ (331,809)
Net loss per common share—basic and diluted	$ (0.38)	$ (0.48)
Weighted average shares outstanding—basic and diluted	759,273,550	695,878,859

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

	Note	Three Months Ended June 30, 2023	2022
Net loss		**$ (327,845)**	**$ (353,784)**
Adjustments:			
Cost of revenues			
Amortization of intangible assets	(1)	2,370	742
Share-based compensation	(2)	38	—
Research and development:			
Share-based compensation	(2)	7,953	12,243
Depreciation and amortization	(3)	1,489	1,070
Selling, general and administrative:			
Share-based compensation	(2)	41,192	60,551
Depreciation and amortization	(3)	1,980	866
Other:			
Change in fair value of investments	(4)	7,564	24,547
Change in fair value of debt and liability instruments	(5)	54,512	41,213
Estimated income tax impact from adjustments	(6)	(732)	1,873
Adjusted net loss (Non-GAAP)		**$ (211,479)**	**$ (210,679)**

	Note	Three Months Ended June 30, 2023	2022
Research and development expenses		**$ 125,133**	**$ 135,830**
Adjustments:			
Share-based compensation	(2)	7,953	12,243
Depreciation and amortization	(3)	1,489	1,070
Adjusted research and development expenses (Non-GAAP)		**$ 115,691**	**$ 122,517**

	Note	Three Months Ended June 30, 2023	2022
Selling, general and administrative expenses		**$ 156,190**	**$ 149,072**
Adjustments:			
Share-based compensation	(2)	41,192	60,551
Depreciation and amortization	(3)	1,980	866
Adjusted selling, general and administrative expenses (Non-GAAP)		**$ 113,018**	**$ 87,655**

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 (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 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 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, August 14, 2023, to report its financial results for the first quarter ended June 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 is concentrated in inflammation and immunology and 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; and RVT-3101, an anti-TL1A antibody in development for ulcerative colitis and Crohn's disease, in addition to several other therapies in various stages of clinical development. 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, visit 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 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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