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 15, 2022

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.)**

Suite 1, 3rd Floor
11-12 St. James's Square
London SW1Y 4LB
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 Stock Market LLC**
Redeemable warrants, each whole warrant exercisable for one Common Share	**ROIVW**	**The Nasdaq Stock Market LLC**

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 15, 2022, Roivant Sciences Ltd. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 2022. 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 15, 2022
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 15, 2022

Roivant Sciences Reports Financial Results for the First Quarter Ended June 30, 2022 and Provides Business Update

- *Early launch data for VTAMA® (tapinarof) with approximately 14,000 prescriptions written by more than 3,000 unique prescribers in initial eleven weeks of launch shows strong demand for first topical novel chemical entity for plaque psoriasis in 25 years*
- *The Journal of the American Academy of Dermatology (JAAD) published the Phase 3 long-term extension study highlighting the unique mechanism for the remittive effect of VTAMA showing mean duration off-therapy for patients achieving PGA=0 was 130 days*
- *Dermavant's Japanese partner reported positive Phase 3 data for tapinarof for the treatment of atopic dermatitis (AD), including statistically significant results on the IGA and EASI scores, and plans to submit for approval in Japan*
- *Enrollment in Priovant's potentially registrational trial for brepocitinib in systemic lupus erythematosus (SLE) is expected to complete in August 2022, and topline data is on track to be announced in the second half of calendar year 2023*
- *Amy Mahery has joined Roivant as Chief Commercial Officer from EMD Serono*
- *On September 28, Roivant will host an investor day, providing updates on the ongoing VTAMA launch in psoriasis, clinical development at the Vants and continued progress from Roivant Discovery*

BASEL, Switzerland, LONDON, NEW YORK and BOSTON, August 15, 2022 – Roivant Sciences Ltd. (Nasdaq: ROIV), a next-generation biopharmaceutical company dedicated to improving the delivery of healthcare to patients, today reported its financial results for the first quarter ended June 30, 2022 and provided an update on the Company's operations.

Roivant's Chief Executive Officer, Matt Gline, noted: "I'm excited by the strong early signals we're seeing from the ongoing VTAMA launch in psoriasis, including approximately 14,000 prescriptions in the first eleven weeks. The recent positive topline results from Torii Pharmaceutical and Japan Tobacco's study of tapinarof in atopic dermatitis underscore our conviction in VTAMA's potential in AD as our own Phase 3 trials progress. We are also pleased with recent execution across the rest of our pipeline, including the continued progress in our pivotal trials at Immunovant and Priovant. We are proud to advance the development of these important medicines for patients."

Roivant also announced today that Amy Mahery will be joining the company as Chief Commercial Officer and will serve as a member of the leadership team. Amy has more than twenty years of industry experience and has been involved in the commercialization and launch of therapies across oncology, neurology and immunology. Most recently, she was the Senior Vice President and Head of the Global Business Franchise, Neurology and Immunology (N&I) at EMD Serono, where she led commercial strategy for the N&I portfolio from clinical development to launch and late lifecycle.

On September 28, Roivant will host an investor day, at which the Company will provide updates on the ongoing VTAMA launch in psoriasis, clinical development at the Vants and continued progress in drug discovery. The webcast for this virtual event will begin at 11 a.m. EDT, and participants can register to attend at https://hopin.com/events/roivantinvestorday2022/registration.

Recent Developments

- **Dermavant**: Since its launch in late May, VTAMA has had approximately 14,000 prescriptions written by more than 3,000 unique prescribers based on the latest available IQVIA data through August 5 for prescriptions and July 29 for prescribers. VTAMA became the most prescribed branded topical for the treatment of psoriasis in the U.S. within eight weeks of launch. In July, Torii Pharmaceutical and Japan Tobacco announced positive topline results from their Phase 3 study of tapinarof in atopic dermatitis. In this trial, tapinarof showed statistical superiority to vehicle on the primary endpoint of efficacy, IGA response at week 8. In addition, tapinarof showed statistical superiority to vehicle for EASI achievement rate at week 8, a key secondary endpoint of efficacy. There were no new observed safety or tolerability findings reported.
- **Priovant:** Priovant expects to complete enrollment for its ongoing potentially registrational global trial evaluating oral brepocitinib for the treatment of SLE in August 2022. Oral brepocitinib is a potential first-in-class dual, selective inhibitor of TYK2 and JAK1 licensed from Pfizer that has been evaluated in 14 completed Phase 1 and Phase 2 trials, including 5 placebo-controlled Phase 2 trials in psoriatic arthritis, plaque psoriasis, ulcerative colitis, alopecia areata and hidradenitis suppurativa that generated statistically significant and clinically meaningful efficacy results. Priovant is also developing oral brepocitinib for the treatment of dermatomyositis, for which it recently initiated a single registrational Phase 3 trial.

Major Upcoming Milestones

- **Dermavant**: Dermavant expects to provide updates on the commercial launch of VTAMA for psoriasis on a periodic basis and to report topline data from the Phase 3 trials of VTAMA for the treatment of atopic dermatitis in the first half of calendar year 2023.
- **Priovant**: Priovant plans to announce topline results from the potentially registrational trial evaluating brepocitinib for the treatment of patients with SLE in the second half of calendar year 2023.
- **Immunovant:** Immunovant plans to initiate two pivotal trials to evaluate batoclimab for the treatment of thyroid eye disease in the second half of calendar year 2022, with topline results expected in the first half of calendar year 2025. Immunovant plans to announce two new indications for batoclimab and the third indication (in addition to MG and TED) it will initiate as a pivotal trial in calendar year 2022 on an investor call scheduled for September 7, 2022.
- **Hemavant:** 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 MDS patients in the second half of calendar year 2023.
- **Kinevant:** Kinevant plans to report topline data from the ongoing Phase 2 trial of namilumab for the treatment of sarcoidosis in the first half of calendar year 2024.

First Quarter Ended June 30, 2022 Financial Summary

Cash Position

As of June 30, 2022, we had cash, cash equivalents and restricted cash of approximately $2.0 billion.

Research and Development Expenses

Research and development (R&D) expenses were $135.8 million for the three months ended June 30, 2022 compared to $78.5 million for the three months ended June 30, 2021. The quarter-over-quarter increase was primarily due to increases in program-specific costs and personnel-related expenses, reflecting the progression of our programs and drug discovery. Additionally, share-based compensation expense increased largely as a result of the ongoing vesting of certain equity instruments for which the liquidity event vesting condition was met upon the closing of the business combination with MAAC in September 2021. We did not recognize share-based compensation expense related to these equity instruments during the three months ended June 30, 2021 as the liquidity event requirement had not been met and was not deemed probable of being met. Non-GAAP R&D expenses were $122.5 million for the three months ended June 30, 2022 compared to $76.2 million for the three months ended June 30, 2021.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were $149.1 million for the three months ended June 30, 2022 compared to $82.8 million for the three months ended June 30, 2021. The quarter-over-quarter increase was primarily due to increases in share-based compensation expense largely as a result of the ongoing vesting of certain equity instruments for which the liquidity event vesting condition was met upon the closing of the business combination with MAAC in September 2021. We did not recognize share-based compensation expense related to these equity instruments during the three months ended June 30, 2021 as the liquidity event requirement had not been met and was not deemed probable of being met. Additionally, SG&A expenses for Dermavant have increased as a result of the commercial launch of VTAMA in May 2022. Non-GAAP SG&A expenses were $87.7 million for the three months ended June 30, 2022 compared to $64.4 million for the three months ended June 30, 2021.

Net Loss

Net loss was $353.8 million for the three months ended June 30, 2022 compared to $101.1 million for the three months ended June 30, 2021. On a per common share basis, net loss was $0.48 for the three months ended June 30, 2022 and $0.13 for the three months ended June 30, 2021. Non-GAAP net loss was $210.7 million for the three months ended June 30, 2022 compared to $133.4 million for the three months ended June 30, 2021.

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

	June 30, 2022	March 31, 2022
Cash, cash equivalents and restricted cash	$ 1,956,469	$ 2,074,034
Total assets	2,600,398	2,585,129
Total liabilities	822,516	523,695
Total shareholders' equity	1,755,391	2,038,943
Total liabilities, redeemable noncontrolling interest and shareholders' equity	2,600,398	2,585,129

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

	Three Months Ended June 30,	
	2022	2021
Revenue, net	$ 4,319	$ 7,735
Operating expenses:		
Cost of revenues	1,726	742
Research and development (includes $12,243 and $1,615 of share-based compensation expense for the three months ended June 30, 2022 and 2021, respectively)	135,830	78,515
Acquired in-process research and development	—	111
Selling, general and administrative (includes $60,551 and $17,654 of share-based compensation expense for the three months ended June 30, 2022 and 2021, respectively)	149,072	82,754
Total operating expenses	286,628	162,122
Loss from operations	(282,309)	(154,387)
Change in fair value of investments	24,547	8,619
Change in fair value of debt and liability instruments	41,213	4,585
Gain on termination of Sumitomo Options	—	(66,472)
Other expense (income), net	1,716	(134)
Loss before income taxes	(349,785)	(100,985)
Income tax expense	3,999	93
Net loss	(353,784)	(101,078)
Net loss attributable to noncontrolling interests	(21,975)	(18,895)
Net loss attributable to Roivant Sciences Ltd.	$ (331,809)	$ (82,183)
Net loss per common share—basic and diluted	$ (0.48)	$ (0.13)
Weighted average shares outstanding—basic and diluted	695,878,859	649,856,203

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

	Note	Three Months Ended June 30, 2022	2021
Net loss		**$ (353,784)**	**$ (101,078)**
Adjustments:			
Cost of revenues			
Amortization of intangible assets	(1)	742	—
Research and development:			
Share-based compensation	(2)	12,243	1,615
Depreciation and amortization	(3)	1,070	743
General and administrative:			
Share-based compensation	(2)	60,551	17,654
Depreciation and amortization	(3)	866	744
Other:			
Change in fair value of investments	(4)	24,547	8,619
Change in fair value of debt and liability instruments	(5)	41,213	4,585
Gain on termination of Sumitomo Options	(6)	—	(66,472)
Estimated income tax impact from adjustments	(7)	1,873	216
Adjusted net loss (Non-GAAP)		**$ (210,679)**	**$ (133,374)**

	Note	Three Months Ended June 30, 2022	2021
Research and development expenses		**$ 135,830**	**$ 78,515**
Adjustments:			
Share-based compensation	(2)	12,243	1,615
Depreciation and amortization	(3)	1,070	743
Adjusted research and development expenses (Non-GAAP)		**$ 122,517**	**$ 76,157**

	Note	Three Months Ended June 30, 2022	2021
Selling, general and administrative expenses		**$ 149,072**	**$ 82,754**
Adjustments:			
Share-based compensation	(2)	60,551	17,654
Depreciation and amortization	(3)	866	744
Adjusted selling, general and administrative expenses (Non-GAAP)		**$ 87,655**	**$ 64,356**

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 (gain) 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 (gain) relating to the measurement and recognition of fair value on a recurring basis of certain liabilities.

(6) Represents the one-time gain on termination of the options held by Sumitomo Pharma Co., Ltd. to purchase Roivant's ownership interest in certain Vants (the "Sumitomo Options").

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

Beginning in the fourth quarter of the fiscal year ended March 31, 2022, the Company no longer excludes from its non-GAAP financial measures acquired IPR&D expenses, which include consideration for the purchase of IPR&D through asset acquisitions and license agreements as well as payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones. Previously, these items were excluded from the Company's non-GAAP financial measures. In conjunction with this change, acquired IPR&D expenses are now reported as a separate line item in its consolidated statements of operations. Prior period amounts have been revised to conform to the current presentation.

There was no acquired IPR&D expense for the three months ended June 30, 2022. For the three months ended June 30, 2021, acquired IPR&D expense was $0.1 million.

Investor Conference Call Information

Roivant will host a live conference call and webcast at 8:00 a.m. ET on Monday, August 15, 2022 to report its financial results for the fiscal quarter ended June 30, 2022 and provide a corporate update.

To access the conference call by phone, please register online using this registration link. A webcast of the call 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 Sciences

Roivant's mission is to improve the delivery of healthcare to patients by treating every inefficiency as an opportunity. Roivant develops transformative medicines faster by building technologies and developing talent in creative ways, leveraging the Roivant platform to launch "Vants" – nimble and focused biopharmaceutical and health technology companies. For more information, please visit www.roivant.com.

Roivant Sciences 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, any commercial potential of our products and product candidates and any pending or potential litigation, including but not limited to our expectations regarding the outcome of any such litigation and costs and expenses associated with such litigation. 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. With the exception of VTAMA, which was approved by FDA for the treatment of plaque psoriasis in adults in May 2022, all products and product candidates referenced in this press release are investigational and subject to health authority approval.

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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