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 14, 2022

Roivant Sciences Ltd.

(Exact Name of Registrant as Specified in Charter)

Bermuda	**001-40782**	**98-1173944**
(State or Other Jurisdiction of Incorporation)	**(CommissionFile 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 November 14, 2022, Roivant Sciences Ltd. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 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 November 14, 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: November 14, 2022

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

- *Expected cash runway extended into the second half of calendar year 2025*
- *First major PBM/payer contract signed for VTAMA, effective October 1*
- *Over 54,000 VTAMA prescriptions written by approximately 6,400 prescribers since launch show strong demand, with fiscal Q2 2022 net product revenue of $5.0 million*
- *Unveiled IMVT-1402, a next generation anti-FcRn which showed deep IgG lowering similar to batoclimab with no or minimal impact observed on albumin and LDL (low-density lipoprotein) levels in animal studies*
- *Completed enrollment for potentially registrational trial for brepocitinib in systemic lupus erythematosus (SLE), with topline data on track to be announced in the second half of calendar year 2023*
- *Federal court denied Moderna's partial motion to dismiss Genevant and Arbutus's pending IP infringement suit*

BASEL, Switzerland, LONDON, NEW YORK and BOSTON, November 14, 2022 – Roivant Sciences Ltd. (Nasdaq: ROIV) today reported its financial results for the second quarter ended September 30, 2022 and provided an update on the Company's operations.

Roivant's chief executive officer, Matt Gline, noted: "This has been a great quarter for Roivant. In addition to VTAMA's strong performance and the enthusiastic feedback we've received from patients and providers, we executed our first major PBM contract. This provides immediate coverage for millions of lives associated with that PBM, establishes a national template for unrestricted access to VTAMA, and supports a paradigm shift to VTAMA as the mainstay of psoriasis therapy. Our fully enrolled potentially registrational SLE study for brepocitinib, which reads out next year, and Immunovant's broadened anti-FcRn portfolio, represent notable progress in our immunology pipeline. Between cost reduction and multiple recent infusions of capital, we've extended our runway into the second half of calendar year 2025 – and we're looking forward to multiple key catalysts between now and then, including many in the next year."

Recent Developments

- **Roivant:** On November 8, priced $150 million total gross primary and secondary offering, consisting of gross primary proceeds to Roivant of $100 million. Roivant continued its cost optimization and pipeline reprioritization initiatives initially announced in June 2022 in order to focus capital on the most valuable and meaningful opportunities in the pipeline, while maintaining the financial flexibility to opportunistically in-license assets. Roivant expects that its consolidated cash, cash equivalents and restricted cash of $1.6 billion at September 30, 2022, or $1.9 billion after giving effect to subsequent Roivant and Immunovant follow-on offerings and anticipated proceeds from the sale of Myovant equity rights to Sumitomo Pharma, along with continued cost savings initiatives, support cash runway into second half of calendar year 2025.
- **Dermavant:** Through November 4, VTAMA has had over 54,000 prescriptions written by approximately 6,400 unique prescribers, based on IQVIA data. For the quarter ended September 30, 2022, Roivant reported VTAMA net product revenue of $5.0 million, representing a gross-to-net yield of approximately 12%. Dermavant also entered into a reimbursement contract with one of the three largest PBMs, effective October 1, 2022. Finally, Dermavant announced results from its maximal use pharmacokinetic study of VTAMA in atopic dermatitis, which showed minimal to no systemic absorption and favorable tolerability when used in pediatric patients down to age two.
- **Priovant**: Completed 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. With over 1,000 patients exposed in these studies, brepocitinib showed a safety and tolerability profile in line with other class agents. Priovant is also developing oral brepocitinib for the treatment of dermatomyositis, for which it recently initiated a single potentially registrational Phase 3 trial.
- **Immunovant:** At Roivant's Investor Day on September 28, Immunovant unveiled IMVT-1402, a next generation anti-FcRn which showed deep IgG lowering similar to batoclimab with no or minimal impact observed on albumin and LDL levels in a head-to-head animal study with batoclimab and placebo. Additionally, on September 7 Immunovant unveiled two new development programs for batoclimab in Graves' disease and chronic inflammatory demyelinating polyneuropathy (CIDP). Immunovant also completed a $75.0 million follow-on offering in October, with leading life sciences investors including Logos Capital, Deep Track Capital, Frazier Life Sciences, TCGX, BVF Partners, and Commodore Capital participating.
- **Genevant:** On November 2, the federal district court in Delaware issued an opinion and order in the patent infringement suit brought by Genevant and Arbutus against Moderna. The court denied Moderna's partial motion to dismiss the suit based on the government-contractor defense under 28 U.S.C. Section 1498, which was an attempt by Moderna to shift liability for an unspecified portion its alleged infringement to the US government and taxpayers. The case is now expected to proceed to the pre-trial discovery phase.
- **Proteovant**: Disclosed today data from its preclinical estrogen receptor (ER) degrader demonstrating equal or better tumor reduction in an *in vivo* model in a head-to-head comparison with the most advanced degrader in its class.
- **Affivant:** Affivant and Affimed jointly unveiled AFVT-2101 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in Boston

on November 8. AFVT-2101 is a tetravalent, bispecific ICE® (innate cell engager) that selectively targets folate receptor alpha (FRα) and CD16A (FcγR3A). AFVT-2101 directs innate immune cells to kill tumor cells selectively and potently with a wide range of FRα expression. Due to the high avidity for CD16A, AFVT-2101 is more efficacious and potent in both antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP) assays than farletuzumab, a monoclonal antibody targeting FRα.

Major Upcoming Milestones

- **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:** 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:** Phase 3 trials of batoclimab in myasthenia gravis (MG) and thyroid eye disease (TED) progressing and expects to have top-line results from the MG trial in the second half of calendar year 2024 and from the two TED trials in the first half of calendar year 2025. A pivotal Phase 2b trial in CIDP is planned to be initiated by the end of calendar year 2022, with initial results from the open label period expected in the first half of calendar year 2024. In Graves' disease, a Phase 2 trial is planned to be initiated in early calendar year 2023 with initial results expected in the second half of calendar year 2023. Immunovant plans to finalize the lead asset and trial design in WAIHA following an expected engagement with the hematology division of the FDA before the end of calendar year 2022. Immunovant plans to submit an IND and initiate a Phase 1 study for IMVT-1402 in early 2023 with initial human data expected in mid-2023; Immunovant believes these Phase 1 results together with strong IgG biomarker data from batoclimab may accelerate the development program for 1402.

- **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:** 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.

Second Quarter Ended September 30, 2022 Financial Summary

Cash Position

As of September 30, 2022, we had cash, cash equivalents and restricted cash of approximately $1.6 billion. Giving effect to Immunovant's October 2022 follow-on offering for $75 million in gross proceeds, Roivant's November follow-on offering for $100 million in gross primary proceeds, and $115 million in expected proceeds from the planned sale of the Myovant top-up shares in connection with the pending acquisition of Myovant by Sumitomo Pharma, Roivant's consolidated cash, cash equivalents and restricted cash would have been approximately $1.9 billion. The Myovant transaction is expected to close in the first calendar quarter of 2023, subject to customary closing conditions.

Research and Development Expenses

Research and development (R&D) expenses were $132.0 million for the three months ended September 30, 2022 compared to $132.1 million for the three months ended September 30, 2021. The quarter-over-quarter decrease was primarily due to a decrease in share-based compensation expense due to the achievement of the liquidity event vesting condition for certain equity instruments upon the closing of the Business Combination with MAAC in September 2021, resulting in the recognition of a one-time catch-up expense. This decrease was offset by increases in personnel-related expenses and program-specific costs, reflecting the progression of our programs and drug discovery. Non-GAAP R&D expenses were $123.3 million for the three months ended September 30, 2022 compared to $103.2 million for the three months ended September 30, 2021.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were $157.7 million for the three months ended September 30, 2022 compared to $437.8 million for the three months ended September 30, 2021. The quarter-over-quarter decrease was primarily due to a decrease in share-based compensation expense, partially offset by higher selling, general and administrative expenses at Dermavant as a result of the commercial launch of VTAMA. The decrease in share-based compensation resulted from the achievement of the liquidity event vesting condition for certain equity instruments upon the closing of the Business Combination with MAAC in September 2021, resulting in the recognition of a one-time catch-up expense. This decrease was partially offset by continued vesting of the equity instruments. Non-GAAP SG&A expenses were $101.5 million for the three months ended September 30, 2022 compared to $68.0 million for the three months ended September 30, 2021.

Net Loss

Net loss was $315.9 million for the three months ended September 30, 2022 compared to $225.6 million for the three months ended September 30, 2021. On a per common share basis, net loss was $0.42 for the three months ended September 30, 2022 and $0.32 for the three months ended September 30, 2021. Non-GAAP net loss was $226.8 million for the three months ended September 30, 2022 compared to $290.0 million for the three months ended September 30, 2021.

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

	September 30, 2022	March 31, 2022
Cash, cash equivalents and restricted cash	$ 1,612,646	$ 2,074,034
Total assets	2,215,534	2,585,129
Total liabilities	701,385	523,695
Total shareholders' equity	1,514,149	2,038,943
Total liabilities, redeemable noncontrolling interest and shareholders' equity	2,215,534	2,585,129

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,	
	2022	2021	2022	2021
Revenue, net	$ 12,533	$ 13,987	$ 16,852	$ 21,722
Operating expenses:				
Cost of revenues	3,641	6,381	5,367	7,123
Research and development (includes $7,417 and $28,157 of share-based compensation expense for the three months ended September 30, 2022 and 2021 and $19,660 and $29,772 for the six months ended September 30, 2022 and 2021, respectively)	131,995	132,098	267,825	210,613
Acquired in-process research and development	—	122,161	—	122,272
Selling, general and administrative (includes $54,479 and $369,155 of share-based compensation expense for the three months ended September 30, 2022 and 2021 and $115,030 and $386,809 for the six months ended September 30, 2022 and 2021, respectively)	157,663	437,776	306,735	520,530
Total operating expenses	293,299	698,416	579,927	860,538
Loss from operations	(280,766)	(684,429)	(563,075)	(838,816)
Change in fair value of investments	54,678	(32,273)	79,225	(23,654)
Gain on sale of investment	—	(443,754)	—	(443,754)
Change in fair value of debt and liability instruments	(13,541)	13,145	27,672	17,730
Gain on termination of Sumitomo Options	—	—	—	(66,472)
Gain on deconsolidation of subsidiary	(16,762)	—	(16,762)	—
Other expense, net	8,615	3,692	10,331	3,558
Loss before income taxes	(313,756)	(225,239)	(663,541)	(326,224)
Income tax expense	2,165	401	6,164	494
Net loss	(315,921)	(225,640)	(669,705)	(326,718)
Net loss attributable to noncontrolling interests	(24,331)	(17,159)	(46,306)	(36,054)
Net loss attributable to Roivant Sciences Ltd.	$ (291,590)	$ (208,481)	$ (623,399)	$ (290,664)
Net loss per common share—basic and diluted	$ (0.42)	$ (0.32)	$ (0.89)	$ (0.45)
Weighted average shares outstanding—basic and diluted	699,888,061	650,225,764	697,894,414	650,041,993

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

	Note	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Six Months Ended September 30, 2022	Six Months Ended September 30, 2021
Net loss		**$ (315,921)**	**$ (225,640)**	**$ (669,705)**	**$ (326,718)**
Adjustments:					
Cost of revenues					
Amortization of intangible assets	(1)	2,200	—	2,942	—
Research and development:					
Share-based compensation	(2)	7,417	28,157	19,660	29,772
Depreciation and amortization	(3)	1,230	780	2,300	1,523
General and administrative:					
Share-based compensation	(2)	54,479	369,155	115,030	386,809
Depreciation and amortization	(3)	1,646	589	2,512	1,333
Other:					
Change in fair value of investments	(4)	54,678	(32,273)	79,225	(23,654)
Gain on sale of investment	(5)	—	(443,754)	—	(443,754)
Change in fair value of debt and liability instruments	(6)	(13,541)	13,145	27,672	17,730
Gain on termination of Sumitomo Options	(7)	—	—	—	(66,472)
Gain on deconsolidation of subsidiary	(8)	(16,762)	—	(16,762)	—
Estimated income tax impact from adjustments	(9)	(2,219)	(156)	(346)	60
Adjusted net loss (Non-GAAP)		**$ (226,793)**	**$ (289,997)**	**$ (437,472)**	**$ (423,371)**

	Note	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Six Months Ended September 30, 2022	Six Months Ended September 30, 2021
Research and development expenses		**$ 131,995**	**$ 132,098**	**$ 267,825**	**$ 210,613**
Adjustments:					
Share-based compensation	(2)	7,417	28,157	19,660	29,772
Depreciation and amortization	(3)	1,230	780	2,300	1,523
Adjusted research and development expenses (Non-GAAP)		**$ 123,348**	**$ 103,161**	**$ 245,865**	**$ 179,318**

	Note	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Six Months Ended September 30, 2022	Six Months Ended September 30, 2021
Selling, general and administrative expenses		**$ 157,663**	**$ 437,776**	**$ 306,735**	**$ 520,530**
Adjustments:					
Share-based compensation	(2)	54,479	369,155	115,030	386,809
Depreciation and amortization	(3)	1,646	589	2,512	1,333
Adjusted selling, general and administrative expenses (Non-GAAP)		**$ 101,538**	**$ 68,032**	**$ 189,193**	**$ 132,388**

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 a one-time gain on sale of investment resulting from the merger of Datavant and CIOX Health in July 2021.

(6) Represents the change in fair value of debt and liability instruments, which is non-cash and primarily includes the unrealized (gain) loss relating to the measurement and recognition of fair value on a recurring basis of certain liabilities.

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

(8) Represents the one-time gain on deconsolidation of a subsidiary.

(9) 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 and six months ended September 30, 2022. For the three and six months ended September 30, 2021, acquired IPR&D expense was $122.2 million and $122.3 million, respectively.

Roivant also announced today that it will participate in three additional upcoming investor conferences:

- Cantor Medical & Aesthetic Dermatology, Ophthalmology & MedTech Conference in Miami from December 7-8. CFO Richard Pulik will participate in the panel "Commercial Successes, Current & Upcoming Launches" at 9:00 a.m. EST on Thursday, December 8
- Jefferies Healthcare Summit in Denver from December 14-15
- 41st Annual J.P. Morgan Healthcare Conference in San Francisco from January 9-12

Investor Conference Call Information

Roivant will host a live conference call and webcast at 8:00 a.m. EST on Monday, November 14, 2022 to report its financial results for the fiscal quarter ended September 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 VTAMA and our other existing and future product candidates, the timing and expectations of potential regulatory submissions, the availability and success of topline results from our ongoing clinical trials, any commercial potential of VTAMA and our other product candidates, including but not limited to the anticipated timeline of commercial coverage of VTAMA, the receipt of proceeds from the expected sale of the Myovant top-up shares to Sumitomo Pharma, 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, and our business strategies, financial condition, and trends, competitive position, potential growth opportunities, and expectations or probabilities for success. 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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