UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

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

Exhibit 99.1

Roivant Sciences Reports Financial Results for the Third Quarter Ended December 31, 2022 and Provides Business Update

- $9.2M in net product revenue from VTAMA reported for the quarter ended December 31, 2022, with nearly 100,000 VTAMA prescriptions written by approximately 8,600 unique prescribers since launch
- VTAMA payor coverage significantly expanded, with 57% of commercial lives now covered
- ADORING 1 and 2 trials evaluating tapinarof in atopic dermatitis fully enrolled, with topline data expected from the first study in March 2023 and the second study in May 2023
- Partnership established with Pfizer to develop RVT-3101, a potentially first-in-class, fully human monoclonal antibody that blocks tumor necrosis factor-like ligand 1A (TL1A)
- Statistically significant and clinically meaningful efficacy results reported at each dose tested in TUSCANY-2, a 245-patient global Phase 2b study evaluating RVT-3101 for the treatment of ulcerative colitis
- Data from the chronic therapy period of the TUSCANY-2 study of RVT-3101 for ulcerative colitis expected in 1H 2023
- Primary equity offering upsized to $230M in gross proceeds following strong investor demand with Roivant cash runway into 2H 2025

BASEL, Switzerland and LONDON and NEW YORK and BOSTON, February 13, 2023 – Roivant Sciences (Nasdaq: ROIV) today reported its financial results for the third quarter ended December 31, 2022, and provided an update on the Company's operations.

Roivant's Chief Executive Officer, Matt Gline, noted: "This past quarter was a significant one for the company. We announced the in-licensing of our potentially first-in-class and best-in-class TL1A program RVT-3101 along with highly encouraging Phase 2 induction data. Earlier this month we completed a $230M equity financing to further advance our TL1A programs in Phase 3 and Phase 2 for ulcerative colitis and Crohn's disease, respectively. Additionally, we reported strong growth in VTAMA net revenue and made significant progress on payor coverage with a majority of commercial lives now covered. These recent developments and our strengthened balance sheet continue to support Roivant's growing leadership in immunological and inflammatory diseases and point to an incredibly catalyst-rich year ahead."

Recent Developments

- **Roivant:** In February, Roivant completed an upsized primary equity offering for $230M in gross proceeds, including the exercise in full of the underwriters' overallotment option following strong investor demand. The company plans to use the net proceeds from the offering principally to fund additional studies of RVT-3101, including the initiation of Phase 3 development in ulcerative colitis and Phase 2 development in other indications. Roivant had consolidated cash, cash equivalents and restricted cash of $1.5B at December 31, 2022, or $1.9B after giving effect to the receipt of the anticipated proceeds from the sale of Myovant equity rights to Sumitomo and the net proceeds from the offering, supporting cash runway into the second half of calendar year 2025.

- **Dermavant:** Through February 10, 2023, nearly 100,000 VTAMA prescriptions have been written by approximately 8,600 unique prescribers, based on IQVIA data. For the quarter ended December 31, 2022, Roivant reported VTAMA net product revenue of $9.2 million, representing a gross-to-net yield of approximately 18%. There has been significant progress on payor coverage with the majority of commercial lives, 57%, now covered. Tapinarof Phase 3 trials in atopic dermatitis, ADORING 1 and ADORING 2, are fully enrolled.

- **Immunovant:** In November 2022, Immunovant initiated a Phase 3 trial to evaluate batoclimab as a treatment for Thyroid Eye Disease (TED). Additionally, in December 2022, IMVT initiated a pivotal Phase 2b trial of batoclimab as a treatment for chronic inflammatory demyelinating polyneuropathy (CIDP).

- **RVT-3101:** In December, Roivant announced a collaboration with Pfizer to develop and commercialize RVT-3101, a potentially first in class, fully human monoclonal antibody that blocks tumor necrosis factor-like ligand 1A (TL1A). In January, Roivant announced data from the induction period of TUSCANY-2, a large 245-patient global Phase 2b study of RVT-3101 against placebo for the treatment of ulcerative colitis. TUSCANY-2 is a 52-week study, with a 12-week induction period comparing different doses of RVT-3101 against placebo, and a 40-week chronic therapy period during which all subjects receive RVT-3101. In the induction period of the TUSCANY-2 study, RVT-3101 demonstrated statistically significant and clinically meaningful efficacy at each dose tested. At the expected Phase 3 dose, 31% of patients achieved clinical remission (modified Mayo) (p=0.01, 20% delta compared to 12% placebo) and 40% of patients achieved endoscopic improvement (p=0.01, 22% delta compared to 19% placebo). At the expected Phase 3 dose, among patients who were positive for a biomarker that was prospectively defined in TUSCANY-2, clinical remission (modified Mayo) and endoscopic improvement rates were 40% (p=0.02, 30% delta compared to 10% placebo) and 56% (p=0.0005, 46% delta compared to 10% placebo), respectively. Approximately 60% of patients were identified as positive for this biomarker. Across all doses and patient groups, RVT-3101 was well tolerated and showed a favorable safety profile.

Major Upcoming Milestones

- **Roivant** plans to announce data from the chronic therapy period of the ongoing TUSCANY-2 study of RVT-3101 for ulcerative colitis in the first half of calendar year 2023.

- **Dermavant** expects to report topline data from the first Phase 3 trial of VTAMA for the treatment of atopic dermatitis in March 2023, with topline data from the second Phase 3 trial expected in May 2023.

- **Immunovant** plans to initiate a Phase 1 clinical trial for IMVT-1402 in early calendar year 2023 contingent on clearance of its Investigational New Drug ("IND") application, with initial data results from this Phase 1 trial expected to be available in mid-calendar year 2023. Immunovant expects to have top-line results from the ongoing MG trial in the second half of calendar year 2024 and from the TED program, consisting of two Phase 3 clinical trials, in the first half of calendar year 2025. Immunovant also expects initial data from period 1 of the Phase 2B trial in CIDP to be available in the first half of calendar year 2024. Immunovant expects to initiate a Phase 2 clinical trial to evaluate batoclimab for the treatment of Graves' disease in early calendar year 2023 with initial results expected in the second 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 fourth quarter of calendar year 2023. Priovant also expects to announce topline results from the Phase 3 trial in 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 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.

Third Quarter Ended December 31, 2022 Financial Summary

Cash Position

As of December 31, 2022, the company had cash, cash equivalents and restricted cash of approximately $1.5 billion. Giving effect to Roivant's February 2023 follow-on offering for $230 million in gross 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 quarter ending March 2023, subject to customary closing conditions.

Research and Development Expenses

Research and development (R&D) expenses decreased by $11.8 million to $125.5 million for the three months ended December 31, 2022 compared to $137.3 million for the three months ended December 31, 2021, primarily due to decreases in share-based compensation of $10.8 million and program-specific costs of $8.0 million, partially offset by increases in personnel-related expenses of $4.1 million and other expenses of $2.8 million.

The decrease of $8.0 million in program-specific costs largely reflects the discontinued development of several programs, including ARU-1801, LSVT-1701, DMVT-502, DMVT-503, DMVT-504, and CVT-TCR-01. These decreases were partially offset by increases reflecting the progression of our programs, including Immunovant's anti-FcRn franchise.

Non-GAAP R&D expenses were $117.4 million for the three months ended December 30, 2022, compared to $118.9 million for the three months ended December 30, 2021.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development increased by $81.6 million to $97.7 million for the three months ended December 31, 2022, compared to $16.1 million for the three months ended December 31, 2021, primarily due to consideration for the purchase of IPR&D of $87.7 million relating to the acquisition of RVT-3101 by a newly formed subsidiary in November 2022. Additionally, the achievement of a development milestone relating to Immunovant's batoclimab program resulted in a one-time milestone expense of $10.0 million. Acquired in-process research and development expense for the three months ended December 31, 2021 was primarily driven by consideration for the purchase of IPR&D of $14.1 million relating to the acquisition of RVT-2001 by Hemavant.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $52.7 million to $168.3 million for the three months ended December 31, 2022, compared to $115.5 million for the three months ended December 31, 2021, primarily due to higher selling, general and administrative expenses at Dermavant as a result of the commercial launch of VTAMA.

Non-GAAP SG&A expenses were $115.9 million for the three months ended December 31, 2022, compared to $61.4 million for the three months ended December 30, 2021. The majority of non-GAAP SG&A expenses of $115.9 million were related to Dermavant's SG&A and ongoing VTAMA commercial launch activities.

Net Loss

Net loss was $384.9 million for the three months ended December 31, 2022, compared to $306.1 million for the three months ended December 31, 2021. On a per common share basis, net loss was $0.49 for the three months ended December 31, 2022 and $0.41 for the three months ended December 31, 2021. Non-GAAP net loss was $297.5 million for the three months ended December 31, 2022, compared to $173.1 million for the three months ended December 31, 2021.

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Selected Balance Sheet Data

(unaudited, in thousands)

	December 31, 2022	March 31, 2022
Cash, cash equivalents and restricted cash	$ 1,541,037	$ 2,074,034
Total assets	2,202,960	2,585,129
Total liabilities	775,822	523,695
Total shareholders' equity	1,427,138	2,038,943
Total liabilities, redeemable noncontrolling interest and shareholders' equity	2,202,960	2,585,129

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Condensed Consolidated Statements of Operations

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

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2022	2021	2022	2021
Revenue, net	$ 17,052	$ 24,341	$ 33,904	$ 46,063
Operating expenses:				
Cost of revenues	3,586	1,384	8,953	8,507
Research and development (includes $6,888 and $17,669 of share-based compensation expense for the three months ended December 31, 2022 and 2021 and $26,548 and $47,441 for the nine months ended December 31, 2022 and 2021, respectively)	125,533	137,345	393,358	347,958
Acquired in-process research and development	97,749	16,105	97,749	138,377
Selling, general and administrative (includes $50,741 and $53,547 of share-based compensation expense for the three months ended December 31, 2022 and 2021 and $165,771 and $440,356 for the nine months ended December 31, 2022 and 2021, respectively)	168,261	115,530	474,996	636,060
Total operating expenses	395,129	270,364	975,056	1,130,902
Loss from operations	(378,077)	(246,023)	(941,152)	(1,084,839)
Change in fair value of investments	(25,948)	38,036	53,277	14,382
Gain on sale of investment	—	—	—	(443,754)
Change in fair value of debt and liability instruments	62,360	23,017	90,032	40,747
Gain on termination of Sumitomo Options	—	—	—	(66,472)
Gain on deconsolidation of subsidiaries	(12,514)	—	(29,276)	—
Other (income) expense, net	(19,898)	(1,029)	(9,567)	2,529
Loss before income taxes	(382,077)	(306,047)	(1,045,618)	(632,271)
Income tax expense	2,819	38	8,983	532
Net loss	(384,896)	(306,085)	(1,054,601)	(632,803)
Net loss attributable to noncontrolling interests	(32,882)	(21,549)	(79,188)	(57,603)
Net loss attributable to Roivant Sciences Ltd.	$ (352,014)	$ (284,536)	$ (975,413)	$ (575,200)
Net loss per common share—basic and diluted	$ (0.49)	$ (0.41)	$ (1.39)	$ (0.87)
Weighted average shares outstanding—basic and diluted	713,319,399	686,589,478	703,054,773	662,268,788

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

	Note	Three Months Ended December 31, 2022	Three Months Ended December 31, 2021	Nine Months Ended December 31, 2022	Nine Months Ended December 31, 2021
Net loss		**$ (384,896)**	**$ (306,085)**	**$ (1,054,601)**	**$ (632,803)**
Adjustments:					
Cost of revenues					
Amortization of intangible assets	(1)	2,228	—	5,170	—
Research and development:					
Share-based compensation	(2)	6,888	17,669	26,548	47,441
Depreciation and amortization	(3)	1,258	778	3,558	2,301
Selling, general and administrative:					
Share-based compensation	(2)	50,741	53,547	165,771	440,356
Depreciation and amortization	(3)	1,664	592	4,176	1,925
Other:					
Change in fair value of investments	(4)	(25,948)	38,036	53,277	14,382
Gain on sale of investment	(5)	—	—	—	(443,754)
Change in fair value of debt and liability instruments	(6)	62,360	23,017	90,032	40,747
Gain on termination of Sumitomo Options	(7)	—	—	—	(66,472)
Gain on deconsolidation of subsidiaries	(8)	(12,514)	—	(29,276)	—
Estimated income tax impact from adjustments	(9)	756	(689)	410	(629)
Adjusted net loss (Non-GAAP)		**$ (297,463)**	**$ (173,135)**	**$ (734,935)**	**$ (596,506)**

	Note	Three Months Ended December 31, 2022	Three Months Ended December 31, 2021	Nine Months Ended December 31, 2022	Nine Months Ended December 31, 2021
Research and development expenses		**$ 125,533**	**$ 137,345**	**$ 393,358**	**$ 347,958**
Adjustments:					
Share-based compensation	(2)	6,888	17,669	26,548	47,441
Depreciation and amortization	(3)	1,258	778	3,558	2,301
Adjusted research and development expenses (Non-GAAP)		**$ 117,387**	**$ 118,898**	**$ 363,252**	**$ 298,216**

	Note	Three Months Ended December 31, 2022	Three Months Ended December 31, 2021	Nine Months Ended December 31, 2022	Nine Months Ended December 31, 2021
Selling, general and administrative expenses		**$ 168,261**	**$ 115,530**	**$ 474,996**	**$ 636,060**
Adjustments:					
Share-based compensation	(2)	50,741	53,547	165,771	440,356
Depreciation and amortization	(3)	1,664	592	4,176	1,925
Adjusted selling, general and administrative expenses (Non-GAAP)		**$ 115,856**	**$ 61,391**	**$ 305,049**	**$ 193,779**

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 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 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 Pharma Co., Ltd. to purchase Roivant's ownership interest in certain Vants (the "Sumitomo Options").

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

(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 condensed consolidated statements of operations. Prior period amounts have been revised to conform to the current presentation.

For the three and nine months ended December 31, 2022, acquired IPR&D expense was $97.7 million. For the three and nine months ended December 31, 2021, acquired IPR&D expense was $16.1 million and $138.4 million, respectively.

Investor Conference Call Information

Roivant will host a live conference call and webcast at 8:00 a.m. EST on Monday, February 13, 2023 to report its financial results for the fiscal quarter ended December 31, 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.

Upcoming Investor Events

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

- SVB Securities Global Biopharma Conference on Tuesday, February 14 including a fireside chat at 12:00 p.m. EST
- Cowen 43rd Annual Health Care Conference on Tuesday, March 7 including a fireside chat at 11:10 a.m. EST and a panel discussion at 12:50 p.m. EST

A live webcast of each presentation will be available under “Events & Presentations” in the Investors section of the Roivant website.

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.

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. Such 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 the terms and completion of the proposed public offering, 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.

Contacts:

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Media

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