# 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 15, 2021**

# 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 per share** | **ROIV** | **The Nasdaq Stock Market LLC** |
| **Redeemable Warrants, each whole warrant exercisable for one Common Share at an exercise price of $11.50 per 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 November 15, 2021, Roivant Sciences Ltd. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 2021. 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 15, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, 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 15, 2021

**Exhibit 99.1**

**Roivant Sciences Reports Financial Results for the Quarter Ended September 30, 2021 and Provides Business Update**

- *Roivant began trading on Nasdaq under "ROIV"; cash balance increased to $2.5 billion.*
- *Dermavant announced final results from the Phase 3 PSOARING 3 long-term extension study of tapinarof in patients with plaque psoriasis (n=763). The study demonstrated 58% of patients who entered the study with a PGA score ≥2 achieved a PGA score of 0 or 1 and long-term use of tapinarof provided improved and durable effects for up to 52 weeks. 41% of patients in the study achieved complete disease clearance; also observed a median remittive effect of approximately four months for those patients who entered the study with a PGA of 0 after tapinarof treatment. Tapinarof was well tolerated consistent with the previously reported interim analysis.*
- *Aruvant released clinical data from third and fourth patients dosed in ongoing Phase 1/2 trial of ARU-1801 in sickle cell disease, showing zero vaso-occlusive events 18 and 12 months after dosing, respectively; to present clinical data at American Society of Hematology on December 13.*

BASEL, Switzerland and LONDON and NEW YORK and BOSTON, Nov. 15, 2021 – 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 second fiscal quarter ended September 30, 2021 and provided an update on the Company's operations.

Roivant's Chief Executive Officer, Matt Gline, noted: "We are looking forward to this new phase of growth as we prepare to launch potential blockbuster tapinarof in psoriasis, with registrational studies in atopic dermatitis also underway. In addition to the studies underway at Dermavant, we expect at least four other programs will enter Phase 2 or Phase 3 trials in 2022, and we are excited to continue advancing our protein degrader programs towards the clinic, as well."

**Recent Developments**

- **Roivant:** Roivant closed its business combination with Montes Archimedes Acquisition Corp. ("MAAC") and concurrent PIPE financing, and Roivant began trading on Nasdaq under the ticker "ROIV." Roivant also announced the appointment of its new Chief Financial Officer, Richard Pulik, who previously served as the Global Head of Business Development & Licensing and Portfolio Management, Oncology at Novartis.
- **Dermavant:** At the 30th EADV Virtual Congress, Dermavant presented final results from the Phase 3 PSOARING 3 long-term extension study of tapinarof in patients with plaque psoriasis. The study results demonstrated that tapinarof was generally well tolerated long term, with a safety profile consistent with the pivotal studies and previously reported interim analysis of data from PSOARING 3. The study demonstrated a high rate of complete disease clearance, with 58.2% of patients who entered the study with a PGA score ≥2 achieving a PGA score of 0 or 1. The study also demonstrated improved and durable results for up to 52 weeks and a median remittive effect off-therapy of approximately four months for patients entering with a PGA score of 0.

- **Aruvant:** At Roivant's Annual R&D Day, Aruvant released clinical data from the third and fourth patients dosed in its ongoing Phase 1/2 trial of ARU-1801 in sickle cell disease. These patients, the first to be dosed with Aruvant's updated manufacturing process, have had zero vaso-occlusive events 18 and 12 months after dosing, respectively. Punam Malik, M.D., Director of the Cincinnati Comprehensive Sickle Cell Center and Program Leader of the Hematology and Gene Therapy Program at the Cincinnati Children's Hospital Medical Center, will present ARU-1801 data at 6:00 to 8:00 PM ET on December 13, 2021 at the American Society of Hematology (ASH) Annual Meeting.
- **Sio Gene Therapies:** Sio Gene Therapies announced positive interim safety and biomarker data from its ongoing Phase 1/2 clinical trial of AXO-AAV-GM1 in GM1 gangliosidosis, showing consistent dose-dependent improvements across biomarker measures and no overt disease progression in six out of seven patients treated across low- and high-dose cohorts.

**Major Upcoming Milestones**

- **Dermavant:** We expect a decision from the FDA on the approval of tapinarof for the treatment of adults with plaque psoriasis in the second quarter of calendar year 2022. We also expect to report topline data from Dermavant's Phase 3 clinical trial of tapinarof for the treatment of atopic dermatitis in the first half of calendar year 2023.
- **Immunovant:** Contingent upon FDA feedback, Immunovant plans to initiate a pivotal trial evaluating batoclimab for the treatment of myasthenia gravis in the early part of calendar year 2022, and re-initiate its programs in thyroid eye disease and warm autoimmune hemolytic anemia. Immunovant also plans to announce at least two new indications and submit INDs with their trial designs to the FDA by August 2022.
- **Aruvant:** We expect Aruvant to report additional clinical data from its ongoing Phase 1/2 trial of ARU-1801 in sickle cell disease patients at ASH, including data that demonstrates how the potent anti-sickling effect of ARU-1801 can translate into robust clinical outcomes.
- **Kinevant:** Kinevant remains on track to initiate its Phase 2 trial evaluating namilumab for the treatment of pulmonary sarcoidosis in the first half of calendar year 2022.
- **Lysovant:** Lysovant remains on track to initiate its multiple ascending dose study of LSVT-1701 in patients with complicated *Staph aureus* bacteremia including infective endocarditis in the first half of calendar year 2022.

**Fiscal Quarter Ended September 30, 2021 Financial Summary**

***Cash Position***

As of September 30, 2021, we had cash and cash equivalents of approximately $2.5 billion. The increase from cash and cash equivalents of approximately $2.0 billion as of June 30, 2021 reflects net cash proceeds of $213.4 million received at the closing of the business combination with MAAC and concurrent PIPE financing, approximately $320 million in cash proceeds from Datavant's merger with Ciox Health (the "Datavant Merger") and funding of the second $100.0 million payment to Proteovant Sciences under a subscription agreement entered into with SK, Inc. in December 2020.

***Research and Development Expenses***

Research and development (R&D) expenses were $254.3 million for the three months ended September 30, 2021 compared to $97.4 million for the three months ended September 30, 2020. The increase was primarily due to an increase in program-specific costs relating to our product candidates, one-time consideration for the purchase of in-process R&D related to an asset acquisition, and an increase in share-based compensation expense due to the achievement of the liquidity event vesting condition for restricted stock units, performance options and capped value appreciation rights upon the closing of the business combination with MAAC, resulting in the recognition of a one-time catch-up expense of $22.9 million. Non-GAAP R&D expenses were $103.9 million for the three months ended September 30, 2021 compared to $50.2 million for the three months ended September 30, 2020.

***General and Administrative Expenses***

General and administrative (G&A) expenses were $437.8 million for the three months ended September 30, 2021 compared to $59.7 million for the three months ended September 30, 2020. The increase was largely due to an increase in share-based compensation expense, primarily as a result of the achievement of the liquidity event vesting condition for restricted stock units, performance options and capped value appreciation rights upon the closing of the business combination with MAAC, resulting in the recognition of a one-time catch-up expense of $350.0 million. Non-GAAP G&A expenses were $68.6 million for the three months ended September 30, 2021 compared to $47.7 million for the three months ended September 30, 2020.

***Gain on Sale of Investment***

Gain on sale of investment resulted from the Datavant Merger in July 2021. At closing of the Datavant Merger, we received approximately $320 million in cash and a minority equity interest in the combined company, which resulted in a gain of $443.8 million.

***Net Loss***

Net loss for the three months ended September 30, 2021 was $225.6 million compared to $53.5 million for three months ended September 30, 2020. On a per common share basis, net loss was $0.32 and $0.06 for the three months ended September 30, 2021 and 2020, respectively. Non-GAAP net loss was $169.2 million for the three months ended September 30, 2021 compared to $96.9 million for the three months ended September 30, 2020.

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

| | September 30, 2021 | March 31, 2021 |
|---|---|---|
| Cash, cash equivalents and restricted cash | $ 2,509,124 | $ 2,141,676 |
| Total assets | 3,102,906 | 2,589,692 |
| Total liabilities | 652,007 | 527,687 |
| Total shareholders' equity | 2,428,408 | 2,039,514 |
| Total liabilities, redeemable noncontrolling interest and shareholders' equity | 3,102,906 | 2,589,692 |

**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, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Revenue, net | $ 13,987 | $ 1,323 | $ 21,722 | $ 2,899 |
| Operating expenses: | | | | |
| Cost of revenues | 6,381 | 715 | 7,123 | 895 |
| Research and development | 254,259 | 97,409 | 332,885 | 156,143 |
| General and administrative | 437,776 | 59,740 | 520,530 | 116,855 |
| Total operating expenses | 698,416 | 157,864 | 860,538 | 273,893 |
| Loss from operations | (684,429) | (156,541) | (838,816) | (270,994) |
| Change in fair value of investments | (32,273) | (84,297) | (23,654) | (125,445) |
| Gain on sale of investment | (443,754) | — | (443,754) | — |
| Change in fair value of debt and liability instruments | 13,145 | 10,148 | 17,730 | 27,273 |
| Gain on termination of Sumitomo Options | — | — | (66,472) | — |
| Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity | — | (28,848) | — | (115,364) |
| Other expense (income), net | 3,692 | (757) | 3,558 | 2,085 |
| Loss before income taxes | (225,239) | (52,787) | (326,224) | (59,543) |
| Income tax expense | 401 | 711 | 494 | 1,932 |
| Net loss | (225,640) | (53,498) | (326,718) | (61,475) |
| Net loss attributable to noncontrolling interests | (17,159) | (18,100) | (36,054) | (22,834) |
| Net loss attributable to Roivant Sciences Ltd. | $ (208,481) | $ (35,398) | $ (290,664) | $ (38,641) |
| Net loss per common share—basic and diluted | $ (0.32) | $ (0.06) | $ (0.45) | $ (0.06) |
| Weighted average shares outstanding—basic and diluted | 650,225,764 | 628,779,048 | 650,041,993 | 628,779,048 |

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

| | Note | Three Months Ended September 30, 2021 | Three Months Ended September 30, 2020 | Six Months Ended September 30, 2021 | Six Months Ended September 30, 2020 |
|---|---|---|---|---|---|
| **Net loss** | | **$ (225,640)** | **$ (53,498)** | **$ (326,718)** | **$ (61,475)** |
| Adjustments: | | | | | |
| Research and development: | | | | | |
| Share-based compensation | (1) | 28,157 | 1,887 | 29,772 | 3,006 |
| Milestone payments | (2) | 40,054 | — | 40,165 | 3,216 |
| In-process research and development | (3) | 82,107 | 45,339 | 82,107 | 45,339 |
| General and administrative: | | | | | |
| Share-based compensation | (1) | 369,155 | 12,027 | 386,809 | 25,186 |
| Other: | | | | | |
| Gain on sale of investment | (4) | (443,754) | — | (443,754) | — |
| Change in fair value of investments | (5) | (32,273) | (84,297) | (23,654) | (125,445) |
| Change in fair value of debt and liability instruments | (6) | 13,145 | 10,148 | 17,730 | 27,273 |
| Gain on sale of Sumitomo Options | (7) | — | — | (66,472) | — |
| Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity | (8) | — | (28,848) | — | (115,364) |
| Estimated income tax impact from adjustments | (9) | (156) | 302 | 60 | 1,511 |
| **Adjusted net loss (Non-GAAP)** | | **$ (169,205)** | **$ (96,940)** | **$ (303,955)** | **$ (196,753)** |

| | Note | Three Months Ended September 30, 2021 | Three Months Ended September 30, 2020 | Six Months Ended September 30, 2021 | Six Months Ended September 30, 2020 |
|---|---|---|---|---|---|
| **Research and development expenses** | | **$ 254,259** | **$ 97,409** | **$ 332,885** | **$ 156,143** |
| Less Adjustments: | | | | | |
| Share-based compensation | (1) | 28,157 | 1,887 | 29,772 | 3,006 |
| Milestone payments | (2) | 40,054 | — | 40,165 | 3,216 |
| In-process research and development | (3) | 82,107 | 45,339 | 82,107 | 45,339 |
| **Adjusted research and development expenses (Non-GAAP)** | | **$ 103,941** | **$ 50,183** | **$ 180,841** | **$ 104,582** |

| | Note | Three Months Ended September 30, 2021 | Three Months Ended September 30, 2020 | Six Months Ended September 30, 2021 | Six Months Ended September 30, 2020 |
|---|---|---|---|---|---|
| **General and administrative expenses** | | **$ 437,776** | **$ 59,740** | **$ 520,530** | **$ 116,855** |
| Less Adjustments: | | | | | |
| Share-based compensation | (1) | 369,155 | 12,027 | 386,809 | 25,186 |
| **Adjusted general and administrative expenses (Non-GAAP)** | | **$ 68,621** | **$ 47,713** | **$ 133,721** | **$ 91,669** |

Notes to non-GAAP measures:

(1) Represents non-cash share-based compensation expense.

(2) Represents one-time development milestone payments.

(3) Represents one-time in-process research and development expense.

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

(5) 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. This is a non-cash loss (gain) that has no direct correlation to the operation of Roivant's business.

(6) 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.

(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 one-time gain on deconsolidation of a subsidiary and the remeasurement of a previously held interest in an unconsolidated entity upon its consolidation.

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

The information presented in this document has been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), unless otherwise noted as non-GAAP. Roivant believes that its presentation of non-GAAP financial measures provides useful supplementary information to and facilitates additional analysis by investors. Management uses certain non-GAAP information internally for its operating, budgeting and financial planning purposes. Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used to supplement an understanding of Roivant's operating results as reported under GAAP. Non-GAAP financial information generally excludes (i) non-cash items, including share-based compensation expense and the change in fair value of debt and liability instruments, (ii) consideration for the purchase of in-process research and development through asset acquisitions and license agreements, including upfront cash payments, the fair value of equity liability instruments issued, and the fair value of certain future contingent consideration payments, and (iii) other items that are considered unusual or not representative of underlying trends of Roivant's business. Non-GAAP measures may be defined and calculated differently by other companies in the same industry. Reconciliations of the non-GAAP financial measures to the most directly comparable GAAP financial measures are provided in the tables above.

**Investor Conference Call Information**

Roivant will host a live conference call and webcast at 8:00 a.m. ET on Monday, November 15, 2021 to report its second quarter 2021 financial results, and provide a corporate update.

To access the live conference call, please dial +1-844-224-1923 (domestic) or +1-214-989-7105 (international) and use conference ID 3545615. 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**

- Jefferies London Healthcare Conference on Wednesday, November 17, 2021 at 12:20 p.m. GMT
- Evercore ISI HealthCONx Conference on Tuesday, November 30, 2021 at 2:15 p.m. ET

**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 product candidates, the availability and success of topline results from our ongoing clinical trials and any commercial potential of our 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. All 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.

**Contacts**

Investors
Roivant Investor Relations
ir@roivant.com

Media
Paul Davis
Roivant Sciences
paul.davis@roivant.com