
**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): September 21, 2021

Roivant Sciences Ltd.

(Exact Name of Registrant as Specified in Charter)

Bermuda
(State or Other Jurisdiction
of Incorporation)

001-40782
(Commission
File Number)

98-1173944
(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 |
|---------------------|----------------------|--|
| N/A | N/A | N/A |

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 September 21, 2021, Roivant Sciences Ltd. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended June 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.

| <u>Exhibit No.</u> | <u>Description of Exhibit</u> |
|--------------------|---|
| 99.1 | Roivant Sciences Ltd. Press Release, dated September 21, 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: September 21, 2021

Roivant Sciences Reports First Fiscal Quarter 2021 Financial Results and Provides Business Update

- *Roivant on track to close business combination with Montes Archimedes Acquisition Corp. (“MAAC”) and concurrent PIPE financing, and commence trading on Nasdaq on October 1 under the symbol “ROIV”*
- *Dermavant’s NDA for tapinarof for the treatment of plaque psoriasis accepted for filing by FDA*
- *First patient dosed in Phase 3 Dermavant trial of tapinarof for the treatment of atopic dermatitis*
- *Datavant completed its merger with Ciox Health; at closing, Roivant received approximately \$320 million in cash and a minority equity stake in the combined company*
- *Roivant made a \$200 million strategic investment in Immunovant*
- *On September 28, Roivant will host its annual R&D Day, providing an update on clinical development at the Vants and Roivant’s new small molecule discovery engine*

BASEL, Switzerland, LONDON and NEW YORK, September 21, 2021 – Roivant Sciences Ltd. (“Roivant” or the “Company”), a next-generation biopharmaceutical company dedicated to improving the delivery of healthcare to patients, today reported its financial results for the fiscal quarter ended June 30, 2021 and provided an update on the Company’s operations.

“Over the past quarter we have made significant progress as a business, both at Roivant centrally and across our family of companies,” said Matthew Gline, Chief Executive Officer of Roivant. “I look forward to providing an update on these developments and an overview of key milestones to come at our R&D Day next week.”

On September 28, Roivant will host its annual R&D Day, at which the Company will provide updates on clinical development at the Vants and Roivant’s new small molecule discovery engine. The webcast for this virtual event will begin at 1 p.m. ET and can be accessed at <https://tinyurl.com/Roivant>.

Recent Developments

- **Datavant:** In June 2021, Datavant and Ciox Health entered into a definitive agreement to merge the two companies. The combined entity, named Datavant, is the nation’s largest health data ecosystem, enabling patients, providers, payers, health data analytics companies, patient-facing applications, government agencies and life science companies to securely exchange their patient-level data. The merger closed on July 27, 2021. At closing, Roivant received approximately \$320 million in cash and a minority equity stake in the combined company.
- **Aruvant:** In June 2021, Aruvant announced data published on ARU-2801, an investigational gene therapy, that showed improved survival out to 18 months in hypophosphatasia mice.
- **Immunovant:** In August 2021, Roivant made a \$200 million investment in Immunovant. Following this transaction, Roivant owns 73,398,664 shares of Immunovant common stock, representing approximately a 63.8% ownership interest.
- **Dermavant:** In August 2021, the FDA accepted for filing Dermavant’s NDA for tapinarof for the treatment of plaque psoriasis in adult patients. The FDA has assigned a PDUFA target action date in the second calendar quarter of 2022. In September 2021, Dermavant dosed the first patient in a Phase 3 trial of tapinarof for the treatment of atopic dermatitis.
- **Genevant:** In August 2021, Genevant entered into a global collaboration and license agreement with Takeda for the development and commercialization of novel nonviral gene therapies for up to two rare liver diseases. Genevant will be eligible for up to \$303 million in upfront and potential milestone payments, plus royalties on product sales. This is the second collaboration between Genevant and Takeda.

Major Upcoming Milestones

- **Roivant:** We expect to close our business combination with MAAC, along with a concurrent PIPE financing, and commence trading on Nasdaq on October 1 under the symbol “ROIV.” Assuming no redemptions by MAAC shareholders, the business combination and concurrent PIPE financing are expected to deliver approximately \$575 million in net proceeds to Roivant.

- **Dermavant:** We expect a decision from the FDA on the approval of tapinarof for the treatment of adults with plaque psoriasis in the second calendar quarter of 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 IMVT-1401 for the treatment of myasthenia gravis in the early part of calendar year 2022. Immunovant also plans to announce at least two new indications and submit INDs with their trial designs to the FDA over the next 12 months.
- **Aruvant:** We expect Aruvant to report additional clinical data from the ongoing Phase 1/2 trial of ARU-1801 in sickle cell disease patients in the second half of calendar year 2021.

First Fiscal Quarter 2021 Financial Summary

Research and Development Expenses

Research and development expenses increased by \$19.9 million to \$78.6 million for the three months ended June 30, 2021 compared to \$58.7 million for the three months ended June 30, 2020. The increase is primarily due to an increase in personnel-related expenses, which is partially driven by additional headcount to support drug discovery efforts using our computational discovery technology and targeted protein degradation platform, following the acquisition of Silicon Therapeutics in March 2021 and Oncopia Therapeutics, Inc. in November 2020.

General and Administrative Expenses

General and administrative expenses increased by \$25.6 million to \$82.8 million for the three months ended June 30, 2021 compared to \$57.1 million for the three months ended June 30, 2020. The increase was primarily due to increases in professional and transaction fees, personnel-related expenses and share-based compensation expense.

Capital Resources

As of June 30, 2021, we had cash and cash equivalents of approximately \$2.0 billion.

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

| | <u>June 30, 2021</u> | <u>March 31, 2021</u> |
|--|----------------------|-----------------------|
| Cash, cash equivalents and restricted cash | \$ 2,008,377 | \$ 2,141,676 |
| Total assets | 2,454,697 | 2,589,692 |
| Total liabilities | 474,865 | 527,687 |
| Total shareholders' equity | 1,957,341 | 2,039,514 |
| Total liabilities, redeemable noncontrolling interest and shareholders' equity | 2,454,697 | 2,589,692 |

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

| | Three Months Ended June 30, | |
|--|------------------------------------|-------------|
| | 2021 | 2020 |
| Revenue, net | \$ 7,735 | \$ 1,576 |
| Operating expenses: | | |
| Cost of revenues | 742 | 180 |
| Research and development | 78,626 | 58,734 |
| General and administrative | 82,754 | 57,115 |
| Total operating expenses | 162,122 | 116,029 |
| Loss from operations | (154,387) | (114,453) |
| Change in fair value of investments | 8,619 | (41,148) |
| Change in fair value of debt and liability instruments | 4,585 | 17,125 |
| Gain on termination of Sumitomo Options | (66,472) | — |
| Gain on deconsolidation of subsidiary | — | (86,516) |
| Other (income) expense, net | (134) | 2,842 |
| Loss before income taxes | (100,985) | (6,756) |
| Income tax expense | 93 | 1,221 |
| Net loss | (101,078) | (7,977) |
| Net loss attributable to noncontrolling interests | (18,895) | (4,734) |
| Net loss attributable to Roivant Sciences Ltd. | \$ (82,183) | \$ (3,243) |
| Net loss per common share—basic and diluted | \$ (0.37) | \$ (0.02) |
| Weighted average shares outstanding—basic and diluted | 222,081,975 | 214,879,058 |

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 matters relating to the merger (the “Business Combination”) pursuant to the Business Combination Agreement, dated as of May 1, 2021, by and among Roivant, Montes Archimedes Acquisition

Corp. (“MAAC”) and Rhine Merger Sub, Inc., as amended on June 9, 2021 and as may be further amended, supplemented or otherwise modified from time to time. 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 proxy statement/prospectus filed with the SEC on August 10, 2021. 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