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): October 28, 2024

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.)

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 Select 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.		

Introductory Note

As previously disclosed in the Current Reports filed by Roivant Sciences Ltd. (the "Company") with the Securities and Exchange Commission on September 18, 2024 and September 23, 2024, Dermavant Sciences Ltd. ("Dermavant"), a subsidiary of the Company, previously entered into an Agreement and Plan of Merger (the "Merger Agreement"), dated as of September 17, 2024, by and among Dermavant, Organon & Co. ("Organon"), Organon Bermuda Ltd., an indirect wholly owned subsidiary of Organon ("Merger Sub"), and the Company, solely in its capacity as the representative of the securityholders of Dermavant. On October 28, 2024, pursuant to the terms of the Merger Agreement, Merger Sub merged with and into Dermavant, with Dermavant continuing as the surviving company and a wholly owned subsidiary of Organon (the "Merger"). In connection with the closing of the Merger, the Company, Dermavant and Organon took certain other actions, as discussed below.

Item 1.02. Termination of a Material Definitive Agreement.

As contemplated by the Merger Agreement, concurrently with the closing of the Merger, Dermavant repaid all amounts outstanding or otherwise payable (including accrued interest and all premiums and exit fees) pursuant to the Credit Agreement, dated as of May 14, 2021 and amended as of May 24, 2024, by and among Dermavant, certain subsidiaries of Dermavant, XYQ Luxco S.À R.L. and U.S. Bank Trust Company, National Association (the "Credit Agreement") and terminated the Credit Agreement in accordance with its terms.

The information set forth in the Introductory Note to this Current Report on Form 8-K is incorporated by reference into this Item 1.02.

Item 7.01. Regulation FD Disclosure.

On October 28, 2024, the Company and Organon issued a joint press release announcing the closing of the Merger. A copy of the joint press release is attached as Exhibit 99.1 hereto and is incorporated by reference herein.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing with the U.S. Securities Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description of Exhibit

<u>99.1</u> Joint Press Release, dated October 28, 2024.

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: October 28, 2024

Exhibit 99.1

Organon Completes Acquisition of Dermavant, including Innovative Dermatologic Therapy, VTAMA® (tapinarof) Cream, 1%

The acquisition expands Organon's dermatology capabilities with a nonbiologic, non-steroidal topical treatment in the U.S.

BASEL, Switzerland and LONDON and NEW YORK, October 28, 2024 (GLOBE NEWSWIRE) – Organon (NYSE: OGN), a global healthcare company with a mission to improve the health of women throughout their lives, today announced the successful completion of its acquisition of Dermavant Sciences Ltd. from Roivant (NASDAQ: ROIV). Dermavant is a company dedicated to developing and commercializing innovative therapeutic solutions in immunodermatology. Please see our prior announcement for a summary of the <u>transaction terms</u>.

VTAMA® (tapinarof) cream, 1%, is a novel nonbiologic, non-steroidal topical therapy approved by the U.S. Food and Drug Administration (FDA) for treatment of mild, moderate, and severe plaque psoriasis in adults with no safety label warnings or precautions and without restrictions on location and duration of use or body surface area. The FDA is reviewing a supplemental New Drug Application (sNDA) for VTAMA cream as a potential treatment for atopic dermatitis (AD) in adults and children two years of age and older, with Prescription Drug User Fee Act (PDUFA) action expected in the fourth quarter of calendar year 2024.

Plaque psoriasis and atopic dermatitis-commonly known as eczema-are common chronic inflammatory skin diseases affecting millions of people in the U.S. and around the globe. 1,2 Psoriasis presents a significant impact to quality of life and atopic dermatitis is associated with a higher disease burden for women compared to men. 3,4

¹ Armstrong, A., Mehta, M., Schupp, C., Gondo, C., Bell, S., Griffiths, C. Psoriasis Prevalence in Adults in the United States. JAMA Dermatol. 2021 Aug; 157(8):1-7. doi:10.1001/jamadermatol.2021.2007

² Eczema Prevalence. National Eczema Foundation. <u>Eczema Prevalence, Quality of Life and Economic Impact.</u>

⁴ Urban, K., Chu, S., Giesey, RL., Mehrmal, S., Uppal, P., Nedley, N., Delost, GR. The Global, Regional, and National Burden of Atopic Dermatitis in 195 Countries and Territories: An ecological study from the Global Burden of Disease Study 2017. 2021 Mar; 2: 12-18. JAAD International. doi: https://doi.org/10.1016%2Fj.jdin.2020.10.002. https://doi.org/10.1016%2Fj.jdin.2020.10.002. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8362298/

"The future of dermatology depends on innovative treatments like VTAMA, and Organon's acquisition of Dermavant allows us to further expand our existing portfolio of established brands and biosimilar dermatology treatments," said Kevin Ali, Chief Executive Officer of Organon. "Integrating the expertise of Dermavant into Organon's U.S. organization marks the beginning of a new chapter in dermatology. We are excited to bring this nonbiologic non-steroidal topical option to the millions of patients suffering from a chronic skin condition like plaque psoriasis and, potentially in the future, atopic dermatitis."

"I would like to thank Kevin and the entire Organon team for their partnership in the acquisition of Dermavant," said Mayukh Sukhatme, MD, President and Chief Investment Officer of Roivant. "This deal represents a true win-win outcome for Organon and Roivant in our mutual goal to address patient needs and is emblematic of Roivant's ability to form non-traditional, value-enhancing collaborations on important medicines. We believe that Organon's strong global commercial footprint will maximize the impact of VTAMA for patients globally, and we are excited to continue to share meaningfully in the success of VTAMA along the way."

About VTAMA® (tapinarof) cream, 1%

VTAMA cream is a non-steroidal once-daily topical treatment. The safety and effectiveness of VTAMA cream was evaluated in randomized, double-blind, vehicle-controlled trials, PSOARING-1 and 2 for plaque psoriasis. The safety and efficacy of VTAMA for the treatment of atopic dermatitis was also evaluated in ADORING-1 and ADORING-2 Phase III clinical studies and is currently under review with the FDA.

Important Safety Information

Indication: VTAMA® (tapinarof) cream, 1% is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults. VTAMA cream is for use on the skin (topical) only. Do not use VTAMA cream in your eyes, mouth, or vagina. Adverse Events: The most common adverse reactions (incidence \geq 1%) in subjects treated with VTAMA cream were folliculitis (red raised bumps around the hair pores), nasopharyngitis (pain or swelling in the nose and throat), contact dermatitis (skin rash or irritation, including itching and redness, peeling, burning, or stinging), headache, pruritus (itching), and influenza (flu).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

See full Prescribing Information and Patient Information.

About Organon

Organon is an independent global healthcare company with a mission to help improve the health of women throughout their lives. Organon's diverse portfolio offers more than 60 medicines and products in women's health, biosimilars, and a large franchise of established medicines across a range of therapeutic areas. In addition to Organon's current products, the company invests in innovative solutions and research to drive future growth opportunities in women's health and biosimilars. In addition, Organon is pursuing opportunities to collaborate with biopharmaceutical partners and innovators looking to commercialize their products by leveraging its scale and agile presence in fast growing international markets.

Organon has geographic scope with significant reach, world-class commercial capabilities, and approximately 10,000 employees with headquarters located in Jersey City, New Jersey.

For more information, visit http://www.organon.com and connect with us on LinkedIn, Instagram, X (formerly known as Twitter) and Facebook.

Cautionary Note Regarding Forward-Looking Statements

Except for historical information, this press release includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, statements about management's expectations about Organon's acquisition of Dermavant (including statements regarding the timing, benefits, and financial impact of such acquisition), potential regulatory approvals and other actions relating to VTAMA (including the expected timeframe thereof), and Organon's expected financial results and condition. Forward-looking statements may be identified by words such as "pursuing," "foresees," "future," "potential," "potentially," "expected," "expects," "will" or words of similar meaning. These statements are based upon the current beliefs and expectations of Organon's management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, an inability to execute on our business development strategy or realize the benefits of our acquisition of Dermayant or any other planned acquisitions; weakening of economic conditions that could adversely affect the level of demand for Dermayant's products; the risk that the business will not be integrated successfully; risks related to the ability to realize the anticipated benefits of the acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the ability to retain key personnel; unknown liabilities; the risk of litigation and/or regulatory actions related to the completed acquisition; pricing pressures globally, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general; an inability to fully execute on Organon's product development and commercialization plans in the United States, Europe, and elsewhere internationally; an inability to adapt to the industry-wide trend toward highly discounted channels; changes in tax laws or other tax guidance which could adversely affect Organon's cash tax liability, effective tax rates, and results of operations and lead to greater audit scrutiny; expanded brand and class competition in the markets in which Organon operates; and governmental initiatives that adversely impact Organon's marketing activities. Organon undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forwardlooking statements can be found in Organon's filings with the Securities and Exchange Commission ("SEC"), including Organon's most recent Annual Report on Form 10-K and subsequent SEC filings, available at the SEC's Internet site www.sec.gov. References and links to websites have been provided for convenience, and the information contained on any such website is not a part of, or incorporated by reference into, this press release. Organon is not responsible for the contents of third-party websites.

About Roivant

Roivant is a biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Roivant's pipeline includes IMVT-1402 and batoclimab, fully human monoclonal antibodies targeting FcRn in development across several IgG-mediated autoimmune indications; brepocitinib, a potent small molecule inhibitor of TYK2 and JAK1 in development for the treatment of dermatomyositis and non-infectious uveitis; and mosliciguat, an inhaled soluble sGC activator in development for pulmonary hypertension associated with interstitial lung disease, in addition to other clinical stage molecules. We advance our pipeline by creating nimble subsidiaries or "Vants" to develop and commercialize our medicines and technologies. Beyond therapeutics, Roivant also incubates discovery-stage companies and health technology startups complementary to its biopharmaceutical business. For more information, www.roivant.com.

Roivant 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 following applicable regulatory approvals. In addition, any statements that refer to projections, forecasts or other characterizations of future events, results or circumstances, including any underlying assumptions, are forward-looking statements. Actual results may differ materially from those contemplated in these statements due to a variety of risks, uncertainties and other factors, including (i) the possibility that the transaction may involve unexpected costs or liabilities, (ii) the risk that disruptions from the transaction will harm relationships with employees, customers and suppliers and other business partners or (iii) the risk that the achievement of the specified milestones or royalties described in the definitive agreement for the transaction may take longer to achieve than expected or may never be achieved and the resulting contingent milestone payments or royalties may never be realized.

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 Keyur Parekh keyur.parekh@roivant.com

Media Stephanie Lee stephanie.lee@roivant.com