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): May 16, 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 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 8.01. Other Events

On May 16, 2023, Roivant Sciences Ltd. issued a press release announcing positive topline results from Dermavant's ADORING 1 Phase 3 trial of VTAMA for atopic dermatitis. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference into this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Roivant Sciences Ltd. Press Release, dated May 16, 2023
104	Cover Page Interactive Data File (embedded with 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: May 16, 2023

Exhibit 99.1

Roivant Reports Positive Topline Results from ADORING 1, the Second Atopic Dermatitis Phase 3 Trial of VTAMA® (tapinarof) Cream, 1% in Adults and Children as Young as 2 Years Old

- ADORING 1 met the primary and all secondary endpoints, consistent with the positive topline results from the Phase 3 ADORING 2 trial reported in March, marking Roivant's 10th consecutive positive Phase 3 study since 2019
- 45.4% of subjects receiving VTAMA achieved the primary endpoint of vIGA-AD™ response of clear (0) or almost clear (1) with at least a 2-grade improvement from baseline at Week 8, versus 13.9% on vehicle (P<0.0001)
- All secondary endpoints were met with statistical significance, including 55.8% of subjects treated with VTAMA who achieved the key secondary endpoint of EASI75 at Week 8 (P<0.0001)
- Meaningful impact on the exploratory endpoint of pruritus (itch) was demonstrated with 61.1% of subjects, with a baseline PP-NRS score ≥4, achieving a ≥4-point reduction in the PP-NRS at Week 8 (P<0.0001)
- 91% of subjects from ADORING 1 & 2 elected to enroll into the Phase 3 ADORING 3 open-label, long-term safety study*
- sNDA for VTAMA in atopic dermatitis anticipated to be filed with the FDA in Q1 2024

LONG BEACH, Calif., and BASEL, Switzerland, May 16, 2023 – Dermavant Sciences, a Roivant Sciences (Nasdaq: ROIV) company dedicated to developing and commercializing innovative therapeutics in immuno-dermatology, today announced positive results from ADORING 1, the second of two double-blind, randomized, vehicle-controlled Phase 3 studies to evaluate the efficacy and safety of topical VTAMA® (tapinarof) cream, 1% in adults and pediatric subjects down to 2 years old with moderate to severe atopic dermatitis (AD).

In ADORING 1 (N=407), VTAMA met the primary endpoint of the trial and demonstrated highly statistically significant improvement in the Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD™) score of clear (0) or almost clear (1) with at least a 2-grade improvement from baseline at Week 8 (P<0.0001).

Additionally, VTAMA demonstrated highly statistically significant improvement in the proportion of subjects with ≥75% improvement in the Eczema Area and Severity Index (EASI75) from baseline at Week 8 (P<0.0001), a key secondary endpoint. Subjects 12 years and older receiving VTAMA also experienced a statistically significant improvement in itch with a ≥4-point reduction in the patient reported Peak Pruritus Numeric Rating Scale (PP-NRS) (P=0.0366), another key secondary endpoint.

Table 1: ADORING 1 and ADORING 2 Phase 3 Trials – Primary and Key Secondary Endpoints

	ADORING 1 Week 8			**ADORING 2** Week 8		
Endpoint	VTAMA 1% QD	Vehicle QD	P Value	VTAMA 1% QD	Vehicle QD	P Value
vIGA-AD success[1]	45.4%	13.9%	<0.0001	46.4%	18.0%	<0.0001
EASI75[2]	55.8%	22.9%	<0.0001	59.1%	21.2%	<0.0001
≥4-point reduction in PP-NRS[3]	55.8%	34.2%	0.0366	52.8%	24.1%	0.0015

[1]Primary Endpoint: Proportion of subjects who achieved a vIGA-AD score of clear (0) or almost clear (1) with at least a 2-grade improvement from baseline at Week 8.
[2]Secondary Endpoint: Proportion of subjects with ≥75% improvement in EASI from baseline at Week 8.
[3]Secondary Endpoint: Proportion of subjects ≥12 years old with a baseline PP-NRS score ≥4 who achieved ≥4-point reduction in the PP-NRS from baseline at Week 8.

Importantly, when PP-NRS was assessed across the entire VTAMA treated population, 61.1% (P<0.0001) experienced a statistically significant improvement in itch, a highly prevalent symptom among AD sufferers.

Both adult and pediatric AD subjects down to 2 years of age receiving VTAMA in the ADORING trials did so at the same dose and dose regimen as currently approved for adults with plaque psoriasis. Subject to FDA approval in AD, the company believes this could be a key manufacturing, supply chain, and commercial advantage, offering simplicity of treatment to patients, physicians, pharmacists, and payers, regardless of plaque psoriasis or atopic dermatitis diagnosis.

“I am extremely proud to share the positive results from ADORING 1, the second of our two Phase 3 pivotal trials with VTAMA in adults and children as young as 2 years old with moderate to severe atopic dermatitis,” said Philip M. Brown, MD, JD, Chief Medical Officer at Dermavant. “Similar to our ADORING 2 data, VTAMA hit all its primary and secondary endpoints. Subject to FDA approval, we believe that the positive safety and efficacy profile of VTAMA, combined with its treatment simplicity, has the potential to change the approach in the way patients are treated. The success of the ADORING studies marks a significant milestone for the entire Dermavant team, and I would like to extend my heartfelt thanks to the patients and investigators involved in our clinical studies.”

VTAMA is a novel, aryl hydrocarbon receptor agonist, in development as a once-daily, steroid-free, and cosmetically elegant topical cream for the treatment of AD. In the U.S., VTAMA is currently approved for the topical treatment of plaque psoriasis in adults.

Topline Results

In ADORING 1, adult and pediatric subjects down to 2 years of age with moderate to severe AD were randomized at a 2:1 ratio to receive once daily (QD) treatment with VTAMA or vehicle cream.

- At Week 8, 45.4% of subjects treated with VTAMA in ADORING 1 achieved the primary endpoint of a vIGA-AD of clear (0) or almost clear (1) with at least a 2-grade improvement from baseline at Week 8 ($P<0.0001$).
- Also at Week 8, 55.8% of subjects treated with VTAMA in ADORING 1 achieved the key secondary endpoint of the proportion of subjects with ≥75% improvement in EASI ($P<0.0001$).
- 55.8% of subjects ≥12 years old, with a baseline PP-NRS score ≥4, achieved a ≥4-point reduction in the PP-NRS at Week 8 ($P=0.0366$).
- Importantly, VTAMA data indicated no new safety or tolerability signals in this population including children as young as 2 years old. Adverse events were mostly mild to moderate with a low study discontinuation rate due to adverse events (1.9% VTAMA vs. 3.6% vehicle).
- Adverse events of special interest included contact dermatitis (1.5% VTAMA vs. 2.2% vehicle) and follicular event (10.0% VTAMA vs. 0.7% vehicle).

“Atopic dermatitis affects a significant number of children, and its prevalence continues to grow. Given the increasing need for an effective and well-tolerated, non-steroidal topical treatment option for the pediatric population, the efficacy and safety data from ADORING 1 results are encouraging and, combined with the positive results from the maximal usage pharmacokinetics (MUPK) study, VTAMA appears to have the potential to bring relief to children suffering from this disease,” said Adelaide A. Hebert, MD, professor and chief of pediatric dermatology at McGovern Medical School at UTHealth Houston and Children’s Memorial Hermann. “The prevalence of itch as an associated symptom makes this condition extremely burdensome not only to the patients suffering from AD, but also their families. In this regard, the itch data from ADORING 1, much like that from ADORING 2, emphasizes VTAMA’s effectiveness when it comes to disease control and VTAMA’s potential to reduce one of atopic dermatitis’ most burdensome symptoms.”

“It is a really exciting time for patients suffering from atopic dermatitis and clinicians who treat them. The positive topline data from ADORING 1 taken together with the positive results previously shown in ADORING 2 indicate that VTAMA has potential as a new non-steroidal topical medication option in atopic dermatitis, that can be used anywhere on the body surface, including sensitive areas, for both adults and children as young as two years old,” said Jonathan Silverberg, MD, PhD, MPH, Professor of Dermatology at The George Washington University School of Medicine and Health Sciences in Washington, DC., and the Director of Clinical Research and Contact Dermatitis.

Dermavant recently released highly favorable results from a pediatric maximal usage pharmacokinetics (MUPK) study of VTAMA in AD. The study demonstrated minimal-to-no systemic exposure despite maximal use in subjects with extensive AD. Subjects were as young as 2 years old with up to 90% body surface area (BSA) affected with a mean BSA of 43%.

On May 24, 2022, Dermavant announced the FDA approved VTAMA® (tapinarof) cream, 1% for the treatment of adult plaque psoriasis. The approval made VTAMA the first non-steroidal topical novel chemical entity launched for psoriasis in the U.S. in more than 25 years. VTAMA is approved for mild, moderate, and severe plaque psoriasis - with no label safety warnings or precautions, restrictions on duration of use or body surface area. On July 15, 2022, VTAMA became the #1 prescribed branded topical treatment for plaque psoriasis[1] in adults and to date has over 145,000 prescriptions written with over 10,000 unique prescribers[†].

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 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.

IMPORTANT SAFETY INFORMATION

Indication: VTAMA® (tapinarof) cream, 1% is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults. **Adverse Events**: The most common adverse reactions (incidence ≥ 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 Dermavant's Phase 3 Program for VTAMA cream in Atopic Dermatitis

ADORING is Dermavant's pivotal Phase 3 atopic dermatitis (AD) clinical program for VTAMA® (tapinarof) cream, 1%, which consists of ADORING 1 (NCT05014568) and ADORING 2 (NCT05032859), as well as ADORING 3 (NCT05142774), a 48-week open-label, long-term extension study.

About Atopic Dermatitis

Atopic dermatitis (AD), commonly referred to as eczema, is one of the most common inflammatory skin diseases, affecting over 26 million people in the U.S. alone and up to 10% of adults worldwide. AD occurs most frequently in children, affecting up to 30% worldwide. The disease results in itchy, red, swollen, and cracked skin, often affecting the folds of the arms, back of the knees, hands, face, and neck. Itching is an especially bothersome symptom in AD, and tends to worsen at night, disturbing sleep and causing fatigue, which in children can lead to inattention at school. People with AD may also experience social and emotional distress due to the visibility and discomfort of the disease.

About Dermavant

Dermavant Sciences, a subsidiary of Roivant Sciences, is a biopharmaceutical company dedicated to developing and commercializing innovative therapeutics in immuno-dermatology. Dermavant's focus is to develop therapies that have the potential to address high unmet medical needs while driving greater efficiency in research and clinical development. The company's medical dermatology pipeline includes commercialized, late-stage and earlier-development product candidates that target specific unmet needs in two of the largest growing immuno-dermatology markets, plaque psoriasis and atopic dermatitis, as well as other immunological and inflammatory diseases. Dermavant is marketing VTAMA® (tapinarof) cream, 1%, for the topical treatment of plaque psoriasis in adults. The FDA approved VTAMA for the topical treatment of mild, moderate, and severe plaque psoriasis in May 2022. Dermavant is also developing VTAMA for the treatment of atopic dermatitis in adults and children and released positive topline results from its ADORING 1 and 2 Phase 3 clinical trials in 1H 2023. Dermavant's pipeline includes DMVT-506, a next generation aryl hydrocarbon receptor (AhR) agonist under development as a potential differentiated treatment option for immunological and inflammatory diseases with multiple potential routes of administration.

For more information, please visit www.dermavant.com and follow us on Twitter (@dermavant) and LinkedIn (Dermavant Sciences).

*Dermavant DOF March 2023.

[i]IQVIA National Prescription Audit (NPA) for the 3-month period ending 5/5/2023, reflecting estimates of real-world activity. All rights reserved.
[†]IQVIA NPA for the period 5/20/22 to 5/5/2023, reflecting estimates of real-world activity. All rights reserved.

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