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): March 15, 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 March 15, 2023, Roivant Sciences Ltd. issued a press release announcing positive topline results from Dermavant's ADORING 2 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 March 15, 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: March 15, 2023

Exhibit 99.1

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

- 46.4% of subjects receiving VTAMA cream, 1% achieved the primary endpoint of Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD™) response of clear (0) or almost clear (1) with at least a 2-grade improvement from baseline at Week 8, versus 18.0% on vehicle (P<0.0001)
- All secondary endpoints were met with a high degree of statistical significance, including 59.1% of subjects treated with VTAMA cream who achieved the key secondary endpoint of EASI75 (P<0.0001)
- Meaningful impact on the key secondary endpoint of pruritus (itch) was demonstrated with 52.8% of subjects ≥12 years old, with a baseline PP-NRS score ≥4, achieving a ≥4-point reduction in the PP-NRS at Week 8 (P=0.0015)
- Rollover rate of 92.4% of Phase 3 subjects from this trial into the open-label, long-term safety study*
- Conference call and webcast on March 15, 2023 at 8:00 a.m. ET

LONG BEACH, Calif., and BASEL, Switzerland, March 15, 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 2, one of two double-blind, randomized, vehicle-controlled Phase 3 studies to evaluate the efficacy and safety of topical VTAMA® (tapinarof) cream, 1% in pediatric subjects down to 2 years old and adult subjects with atopic dermatitis (AD).

In ADORING 2 (N=406), VTAMA cream met the primary endpoint of the trial and demonstrated highly statistically significant improvement in the 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 cream demonstrated highly statistically significant improvement in the proportion of subjects with ≥75% improvement in EASI75 from baseline at week 8 (P<0.0001), a key secondary endpoint. Subjects 12 years and older receiving VTAMA cream also experienced a highly statistically significant improvement ≥4-point reduction in Peak Pruritis Numeric Rating Scale (PP-NRS) in itch (P=0.0015), another key secondary endpoint in the study due to its prevalence among AD sufferers.

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

	ADORING 2 Week 8		
Endpoint	VTAMA 1% QD	Vehicle QD	P value
vIGA-AD success[1]	46.4 %	18.0 %	<0.0001
EASI75[2]	59.1 %	21.2 %	<0.0001
≥4-point reduction in PP-NRS[3]	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 achieve ≥ 4-point reduction in the PP-NRS from baseline at Week 8.

Both adult and pediatric AD subjects receiving VTAMA cream, 1% did so at the same dose and dose regimen as already 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 both physicians, pharmacists, and patients, regardless of diagnosis.

“We are highly encouraged by the positive results from ADORING 2, which suggests VTAMA cream can be a potentially important non-steroidal, topical treatment option for atopic dermatitis patients, including children as young as two years old where we know there is a compelling need,” said Philip M. Brown, MD, JD, Chief Medical Officer at Dermavant. “Atopic dermatitis, the most common type of eczema, affects more than 9.6 million children and 16.5 million adults in the United States. The majority of patients diagnosed with atopic dermatitis suffer from severe itching and scratching resulting in skin redness, and damage to the skin barrier, which is why any effective therapeutic for AD needs to tackle the issue of pruritus, especially in a pediatric population.** We now keenly anticipate topline data from our identically designed ADORING 1 trial in May 2023.”

VTAMA cream 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 cream is already approved for the topical treatment of plaque psoriasis in adults.

Topline Results
In ADORING 2, pediatric and adult subjects with atopic dermatitis were randomized at a 2:1 ratio to receive once daily (QD) treatment with VTAMA cream, 1% or vehicle cream.

- At week 8, 46.4% of subjects treated with VTAMA cream in ADORING 2 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, 59.1% of subjects treated with VTAMA cream in ADORING 2 achieved the key secondary endpoint of the proportion of subjects with $\geq$75% improvement in EASI ($P<0.0001$).
- 52.8% of subjects ≥12 years old, with a baseline PP-NRS score ≥4, achieved a ≥4-point reduction in the PP-NRS at Week 8 ($P=0.0015$).
- Importantly, VTAMA cream data indicated no safety or tolerability signals in this population including children as young as 2 years old. Adverse events were mild to moderate with a low study discontinuation rate due to adverse events (1.5% VTAMA vs. 3.0% vehicle).
- Adverse events of special interest included contact dermatitis (1.1% VTAMA vs. 1.5% vehicle) and follicular event (8.9% VTAMA vs. 1.5% vehicle).

“Atopic dermatitis can have a negative impact on the quality of life of diagnosed children as well as their families. Both the efficacy and itch data from the ADORING 2 trial are highly encouraging in this regard, pointing to VTAMA cream as a potential non-steroidal topical treatment option for AD that is safe and well tolerated in children,” said Lawrence Eichenfield, M.D. Chief of Pediatric and Adolescent Dermatology at Rady Children’s Hospital-San Diego. “Importantly, the potential to use the same dose regimen with VTAMA cream for children and adults with AD offers treatment simplicity for prescribers, helped even more by the fact that it is the same regimen already being used for plaque psoriasis.”

“The topline results from ADORING 2 underscore VTAMA cream as a potential well-tolerated therapeutic with a favorable safety profile,” said Linda Stein Gold, M.D., Director of Clinical Research and the Division Head of Dermatology at the Henry Ford Health System. “When one considers this Phase 3 data alongside the recently reported pediatric maximal usage pharmacokinetic (MUPK) AD study, which in treated patients demonstrated minimal-to-no-systemic exposure despite heavy disease burden, VTAMA cream is positioning itself to be a potential two-in-one first-line topical treatment for both atopic dermatitis and plaque psoriasis.”

Dermavant recently released highly favorable results from a pediatric maximal usage pharmacokinetics (MUPK) study of VTAMA cream in AD. The study demonstrated minimal-to-no systemic exposure despite maximal use. In addition, 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 cream the first non-steroidal topical novel chemical entity launched for psoriasis in the U.S. in more than 25 years. VTAMA cream 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 cream became the #1 prescribed branded topical treatment for plaque psoriasis[ı] and to date has over 110,000 prescriptions written with over 9,300 unique prescribers[†].

Conference Call
Roivant will host a conference call and a live webcast on March 15, 2023 at 8:00 am ET to discuss the positive ADORING 2 topline results.

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.

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), an 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 Cream for the topical treatment of mild, moderate, and severe plaque psoriasis in May 2022. Dermavant is also developing VTAMA cream, 1% for the treatment of atopic dermatitis in adults and children and released topline results from its Phase 3 clinical trial, ADORING 2, in March 2023. Dermavant expects to release topline results from its second, identical Phase 3 clinical trial for atopic dermatitis, ADORING 1, in May 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.
** National Eczema Association. Atopic Dermatitis. https://nationaleczema.org/eczema/types-of-eczema/atopic-dermatitis/
[i]IQVIA National Prescription Audit (NPA) for the 3-month period ending 2/24/2023, reflecting estimates of real-world activity. All rights reserved.
[†]NPA for the period 5/20/22 to 3/3/2023, reflecting estimates of real-world activity. All rights reserved.

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