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 24, 2022

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 May 24, 2022, Roivant Sciences Ltd. ("Roivant" or the "Company") held an investor call in relation to the approval by the U.S. Food and Drug Administration ("FDA") of VTAMA® (tapinarof) cream, 1%, an aryl hydrocarbon receptor agonist, indicated for the topical treatment of plaque psoriasis in adults.

The presentation used in connection with the investor call is available on Roivant's investor relations webpage, accessible at https://investor.roivant.com/. The information contained on, or that may be accessed through, our website is not part of, and is not incorporated into, this Current Report on Form 8-K.

The presentation includes certain preliminary financial information for the fiscal year ended March 31, 2022. Specifically, the presentation discloses that Roivant's consolidated cash and cash equivalents balance as of March 31, 2022 was approximately $2.1 billion.

The information in this Item 2.02 is unaudited and preliminary and does not present all information necessary for an understanding of the Company's results of operations for the fiscal year ended March 31, 2022. The audit of the Company's financial statements for the fiscal year ended March 31, 2022 is ongoing and could result in changes to the information in this Item 2.02.

Item 7.01. Regulation FD Disclosure.

The disclosure in Item 2.02 above is hereby incorporated by reference into this Item 7.01.

On May 24, 2022, Roivant's subsidiary, Dermavant Sciences, issued a press release announcing the FDA approval of VTAMA® (tapinarof) cream, 1%, an aryl hydrocarbon receptor agonist, indicated for the topical treatment of plaque psoriasis in adults. A copy of that press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information contained in Items 2.02 and 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 shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press Release, dated May 24, 2022
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: May 24, 2022

Exhibit 99.1

FDA Approves Dermavant's VTAMA® (tapinarof) cream, 1% for the Treatment of Plaque Psoriasis in Adults: First Topical Novel Chemical Entity Launched for Psoriasis in the U.S. in 25 Years

- EFFICACY: In the pivotal Phase 3 clinical trial program, VTAMA cream met all primary and secondary endpoints and demonstrated highly statistically significant improvement versus vehicle in Physician Global Assessment (PGA) score with 36% of patients versus 6% in vehicle in PSOARING 1 and 40% of patients versus 6% in vehicle in PSOARING 2 achieving clear or almost clear with a minimum 2-grade improvement at week 12 ($p<0.0001$ for both trials) -

- REMITTIVE EFFECT: The median duration of clear or almost clear skin was approximately four months after cessation of treatment with VTAMA cream as measured by the time to first worsening while off-therapy during the Phase 3 Long Term Extension (LTE) study for patients who achieved clear skin (PGA 0) on VTAMA cream during PSOARING 1 or 2 -

- DURABILITY: Durability of response up to 52 weeks was demonstrated with intermittent use of VTAMA cream, with no observation of tachyphylaxis (loss of response) while on therapy -

- SAFE AND WELL-TOLERATED, EVEN ON SENSITIVE SKIN AREAS: The safety profile and favorable tolerability of VTAMA cream reported was consistent across PSOARING 1, PSOARING 2 and the Phase 3 LTE, with the majority of adverse events (AEs) localized to site of application, and mild to moderate in nature -

- PATIENT OBSERVATIONS: Patient satisfaction data from the Phase 3 LTE study demonstrated a consistent and positive perception of VTAMA cream across many measures, with 81.7% considering it more effective than prior topical treatments -

- Approved for mild, moderate, and severe psoriasis with no restrictions on duration of use or body surface and remittive effect on-label. Dermavant is prepared for a June 2022 launch with product and sample manufacturing runs completed and a fully staffed commercial team. Conference call and webcast on Tuesday, May 24, 2022, at 8:00 a.m. ET -

LONG BEACH, Calif., and BASEL, Switzerland, May 24, 2022—Dermavant Sciences, a biopharmaceutical company dedicated to developing and commercializing innovative therapeutics in immuno-dermatology, today announced that the U.S. Food and Drug Administration (FDA) has approved VTAMA® (tapinarof) cream, 1%, an aryl hydrocarbon receptor agonist, indicated for the topical treatment of plaque psoriasis in adults. This approval makes VTAMA cream the first and only FDA-approved steroid-free topical medication in its class.

"We are delighted with our FDA-approved label for VTAMA cream, which is for adults with psoriasis, regardless of disease severity, and with an unlimited duration of use. In anticipation of today's approval, we have a fully built commercial infrastructure in place, and I am excited to say we will have product in the channel in the first week of June. As the first and only approved drug in its class in the U.S., the FDA's approval of VTAMA cream provides an effective new non-steroidal treatment option for millions of adults living with plaque psoriasis and represents a major milestone for Dermavant and its stakeholders," said Todd Zavodnick, Chief Executive Officer of Dermavant. "At Dermavant, we are committed to advancing novel, patient-focused innovation in immuno-dermatology. As such, we are proud to have developed a topical treatment in VTAMA cream that provides not only efficacy over 52 weeks but can also be used on all body areas, including on sensitive locations, such as face, skin folds, neck, genitalia, anal crux, inflammatory areas, and axillae. In addition, an approximately four month off-treatment remittive effect (median time to first worsening), leads us to believe that VTAMA cream has the potential to become the preferred topical option for this chronically underserved patient population and among the physicians who treat them."

"Following 20-plus years of minimal innovation in the topical psoriasis treatment space[1,2,3,4], I believe the approval of VTAMA cream is an important step in establishing a new treatment option for adults with mild, moderate and severe plaque psoriasis[5]," said Mark Lebwohl, MD, FAAD, Dean for Clinical Therapeutics and Waldman Professor and Chairman Emeritus of the Kimberly and Eric J. Waldman Department of Dermatology, Icahn School of Medicine at Mount Sinai in New York and lead author of the Phase 3 studies of VTAMA cream published in *The New England Journal of Medicine*. "As a clinician, I'm excited to finally have a versatile, once-daily, steroid-free topical treatment that is backed by extensive clinical trial data supporting its favorable safety and efficacy profile and a demonstrated remittive effect of approximately four months in patients off therapy."

Across PSOARING 1 and PSOARING 2, VTAMA cream demonstrated highly statistically significant improvement in Physician Global Assessment (PGA)[6] score of "clear" (PGA=0) or "almost clear" (PGA=1) with a minimum 2-grade improvement compared with vehicle from baseline at week 12. VTAMA cream also demonstrated a highly statistically significant improvement in all secondary endpoints versus vehicle, including ≥75% Improvement in Psoriasis Area and Severity Index (PASI) score (PASI-75) from baseline at week 12[7]. The adverse event (AE) profile of VTAMA cream reported in both PSOARING 1 and PSOARING 2 demonstrated that the majority of AEs were localized to the site of application and were mild to moderate in nature. The most common AEs of subjects treated with VTAMA cream were folliculitis, nasopharyngitis, and contact dermatitis.

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1 Psomadakis CE, Han G. *J Clin Aesthet Dermatol*. 2019;12(12):28-34

2 National Psoriasis Foundation. Two Centuries of Progress in One Short Timeline. Available at: https://www.psoriasis.org/advance/two-centuries-of-progress-in-one-short-timeline/. Accessed August 20, 2021.

3 Federman DG, Froelich CW, Kirsner RS. *Am Fam Physician*. 1999;59(4):957-962.

4 Goldfarb MT, et al. Mayo Clin Proc. 1987;62:1161-1164.

5 Wu J, Lu M, Veverka K, et al. The journey for US psoriasis patients prescribed a topical: a retrospective database evaluation of patient progression to oral and/or biologic treatment. *Journal of Dermatological Treatment*. 2018;30(5):446-453.

6 Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol*. 2021; 84: 432-70.

7 Lebwohl M, Stein Gold L, Strober B, et al. Poster presentation at the Fall Clinical Dermatology Conference 2020. Oct 29–Nov 1, 2020.

Eligible patients who completed PSOARING 1 or PSOARING 2 could enroll in PSOARING 3, a Phase 3 Long Term Extension (LTE) study, which consisted of an additional 40 weeks of open-label treatment with VTAMA cream, followed by a four-week follow-up. As such, patients who were randomized to VTAMA cream in PSOARING 1 or PSOARING 2 and who also completed the Phase 3 LTE study received VTAMA cream treatment for up to 52 weeks. 92% of patients who completed PSOARING 1 and PSOARING 2 enrolled in the Phase 3 LTE study.

Over 40% of Phase 3 LTE study patients (n=312/763) achieved complete disease clearance (PGA=0) at least once during the study period. For patients randomized to VTAMA cream in PSOARING 1 and PSOARING 2 who achieved a PGA of 0 during the 12-week study and subsequently enrolled in the Phase 3 LTE study (n=73), VTAMA cream demonstrated a remittive effect (maintenance of PGA of 0 or 1 while off therapy) with a median duration to first worsening of approximately four months. Among a larger cohort of patients who either entered the Phase 3 LTE study with a PGA score of 0 or achieved one during the LTE study (n=312), the mean duration of remittive effect off-therapy was 130 days.

In the Phase 3 LTE study, VTAMA cream demonstrated safety and tolerability consistent with PSOARING 1 and PSOARING 2. Treatment emergent adverse events were mostly mild to moderate in nature and restricted to application sites.

Responses to a questionnaire, which were assessed at Phase 3 LTE study completion (week 40 or early termination), demonstrated consistent high rates of satisfaction across all evaluated parameters. Of the 78.5% (n=599) of patients from Phase 3 LTE study who completed the survey: 85.8% of patients felt they could easily manage their psoriasis with VTAMA cream; 83.6% were satisfied with how well VTAMA cream worked; 81.7% considered it more effective than prior topical treatments, and most patients strongly agreed or agreed VTAMA cream absorbed quickly (89.5%), was not greasy (89.0%), and felt good on their skin (79.9%).

“We believe VTAMA cream has the potential to make a meaningful difference in the lives of patients with plaque psoriasis as well as their healthcare providers,” said Philip M. Brown, M.D., J.D., Chief Medical Officer of Dermavant. “We are continuing to leverage our experience and insights with the active ingredient, tapinarof, and potentially other AhR molecules, for potential application to other conditions in dermatology and additional inflammatory and immunology indications.”

In September 2021, Dermavant Sciences announced that it dosed its first patient in a Phase 3, double-blind, vehicle-controlled study of tapinarof cream for the treatment of atopic dermatitis (AD) in adults and children. The Phase 3 clinical program will enroll up to 800 patients across two pivotal trials (ADORING 1 and ADORING 2) to evaluate the safety and efficacy of tapinarof cream, 1% dosed once daily (QD) for 8 weeks versus vehicle cream QD in patients aged 2 years and older diagnosed with moderate to severe AD. The company anticipates announcing topline results from ADORING 1 and ADORING 2 in 1H 2023.

For more information about VTAMA (tapinarof) cream, 1%, visit www.VTAMA.com.

Conference Call

Dermavant will participate in a conference call and a live webcast hosted by Roivant Sciences (Nasdaq: ROIV) on Tuesday, May 24, 2022, at 8:00 a.m. ET / 5:00 a.m. PT to discuss the FDA's approval of VTAMA cream. To access the live conference call, please dial +1-844-224-1923 (domestic) or +1-214-989-7105 (international) and use conference ID 3476029. 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.

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 Psoriasis

Impacting approximately 8 million Americans and 125 million people worldwide, psoriasis is a complex autoimmune disease — meaning that the body's immune system targets and attacks its own cells. Plaque psoriasis, also called psoriasis vulgaris, is the most common form and affects about 80 to 90% of people with psoriasis. In people with light skin, plaque psoriasis is characterized by raised, red or pink patches of skin with silvery-white scale. People with black or brown skin are more likely to have brown or violet-colored patches with silvery-white or gray scale. The scale can be itchy, painful and disfiguring.

Psoriasis can begin at any age, but typically appears around 15 to 25 years of age. The exact cause of psoriasis is not known, but risk factors and triggers may include genetics or a family history of psoriasis, as well as stress, smoking, heavy alcohol consumption and cold or dry weather conditions. People with psoriasis are at an increased risk of developing other health conditions, including psoriatic arthritis, inflammatory bowel disease, hypertension, diabetes, obesity, and depression. In addition to physical symptoms, psoriasis can have a significant impact on a person's quality of life and psychological health.

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 robust medical dermatology pipeline includes both late-stage and earlier-stage-development product candidates the company believes could address important immuno-dermatological conditions, including psoriasis, atopic dermatitis, vitiligo, primary focal hyperhidrosis, and acne. For more information, please visit www.dermavant.com, and follow us on Twitter (@dermavant) and LinkedIn (Dermavant Sciences).

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