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 22, 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 par value per share	**ROIV**	**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 1.01. Entry into a Material Definitive Agreement.

On October 22, 2023, Roivant Sciences Ltd. (the "Company"), the Company's subsidiary Telavant Holdings, Inc. ("Telavant"), Pfizer Inc. ("Pfizer") and Roche Holdings, Inc. (the "Buyer") entered into a Stock Purchase Agreement (the "Purchase Agreement"), pursuant to which the Buyer agreed to acquire all of the issued and outstanding shares of capital stock of Telavant on the terms and subject to the conditions set forth in the Purchase Agreement (the "Transaction"). Telavant holds the rights to RVT-3101, an anti-TL1A antibody in development for ulcerative colitis ("UC") and Crohn's disease. The Company owns 75% of the issued and outstanding shares of common stock and preferred stock of Telavant and Pfizer owns the remaining 25%, in each case on an as-converted basis.

The total consideration to be paid by the Buyer is comprised of (i) $7.1 billion in cash at the closing of the Transaction, subject to certain customary adjustments as set forth in the Purchase Agreement, and (ii) a milestone payment of $150 million in cash payable upon the initiation of a Phase 3 trial in UC, as described in more detail in the Purchase Agreement, in each case to be paid to all of Telavant's equity holders, including holders of restricted stock units, on a pro rata basis relative to their ownership of Telavant prior to the closing of the Transaction. The Transaction was approved by the boards of directors of both the Company and Telavant.

The Transaction is expected to close in the fourth quarter of calendar year 2023 or the first quarter of calendar year 2024. The closing of the Transaction is subject to the satisfaction or waiver of certain customary closing conditions, including certain regulatory approvals. The Purchase Agreement contains customary representations, warranties and covenants related to the Transaction. The Purchase Agreement also includes customary termination provisions and provides that, if the Transaction has not been consummated by July 23, 2024, the parties may terminate the Purchase Agreement and abandon the Transaction.

The representations and warranties of the parties contained in the Purchase Agreement have been made solely for the benefit of the parties to the Purchase Agreement. In addition, such representations and warranties (i) have been made only for purposes of the Purchase Agreement, (ii) have been qualified by confidential disclosures made to the Buyer in connection with the Purchase Agreement, (iii) are subject to materiality qualifications contained in the Purchase Agreement, which may differ from what may be viewed as material by investors, (iv) were made only as of the date of the Purchase Agreement or such other date as is specified in the Purchase Agreement, (v) have been included in the Purchase Agreement for the purpose of allocating risk among the Company, Pfizer and the Buyer rather than establishing matters as facts and (vi) will not survive consummation of the Transaction. The foregoing description of the Purchase Agreement is not complete and is qualified in its entirety by reference to the full text of the Purchase Agreement, a copy of which will be filed as an exhibit to the Company's next quarterly report on Form 10-Q filed with the Securities and Exchange Commission ("SEC") and will be publicly available. In addition, the Company files annual, quarterly and current reports and other information with the SEC, which are available to the public at the SEC's website at www.sec.gov.

Item 8.01. Other Events.

On October 23, 2023, the Company issued a press release announcing the Transaction. A copy of the press release is attached as Exhibit 99.1 hereto and is incorporated by reference herein.

Forward Looking Statements

This communication contains forward-looking statements. Statements in this communication 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. These words may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The Company intends 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. The Company's forward-looking statements include, but are not limited to, statements regarding the Company's or its 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 the Company's products and product candidates, the availability and success of topline results from the Company's ongoing clinical trials, any commercial potential of the Company's products and product candidates, the proposed Transaction, the expected benefits of the proposed Transaction, the expected timing of completion of the proposed Transaction and anticipated future financial and operating performance and results. 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 risk that the conditions to the closing of the proposed Transaction may not be satisfied, (ii) the possibility that the proposed Transaction may involve unexpected costs, liabilities or delays, (iii) the risk that the businesses of the companies may suffer as a result of uncertainty surrounding the proposed Transaction, (iv) the risk that disruptions from the proposed Transaction will harm relationships with employees, customers and suppliers and other business partners or (v) the risk that the achievement of the specified milestone described in the Purchase Agreement may take longer to achieve than expected or may never be achieved and the resulting contingent milestone payment may never be realized, and those factors described in the Company's filings with the SEC, including the Company' current reports on Form 8-K, quarterly reports on Form 10-Q and its latest annual report on Form 10-K filed with the SEC on June 28, 2023 (including under the headings "Forward-Looking Statements" and "Risk Factors"). Moreover, the Company operates 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 the Company's management as of the date of this communication, 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, the Company assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press Release, dated October 23, 2023
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 23, 2023

Exhibit 99.1

Roche Enters Into a Definitive Agreement to Acquire Telavant Including Rights to Novel TL1A Directed Antibody (RVT-3101) for the Treatment of Inflammatory Bowel Disease From Roivant

- Roche will gain the rights to develop, manufacture and commercialize RVT-3101 in the US and Japan for the treatment of inflammatory bowel disease and potentially multiple other diseases
- RVT-3101 is a Phase 3-ready antibody with first-in-class and best-in-disease potential, a novel mode of action and strong Phase 2b data in ulcerative colitis
- Roche will also obtain an option to enter into a global collaboration with Pfizer on a next-generation p40/TL1A directed bispecific antibody, currently in Phase 1
- Under the terms of the agreement, Roche will pay a purchase price of $7.1 billion upfront and a near-term milestone payment of $150 million
- Roivant will host an investor call at 8AM ET on Monday, October 23, 2023, to discuss this transaction

BASEL, Switzerland and LONDON and NEW YORK, October 23, 2023 (GLOBE NEWSWIRE) -- Roivant (Nasdaq: ROIV) announced today the entry into a definitive agreement with Roche (SIX: RO, ROG; OTCQX: RHHBY) to acquire Telavant Holdings, Inc. (Telavant), a Roivant company, owned by Roivant Sciences Ltd. and Pfizer Inc. The agreement includes the development, manufacturing and commercialization rights in the US and Japan for RVT-3101, a novel TL1A directed antibody. RVT-3101 is a promising new therapy in development for people suffering from inflammatory bowel disease, including ulcerative colitis and Crohn's disease. Inflammatory bowel disease is a group of chronic gastrointestinal disorders with almost 8 million people diagnosed worldwide and 80% of all individuals not experiencing lasting remission.[1] Given the antibody's novel mode of action targeting both inflammation and fibrosis, it has potential to be applied in multiple other diseases.

RVT-3101 has been investigated in the TUSCANY-2 phase 2b study in patients with moderate to severe ulcerative colitis. The global, randomized, double-blinded, placebo controlled trial delivered the first long-term, dose finding data in a large number of patients (n=245). The maintenance treatment phase following induction resulted in improved clinical remission (36% at week 56) and endoscopic improvement (50% at week 56) at the proposed Phase 3 dose administered subcutaneously every month. Beyond the efficacy results, the maintenance dosing period of RVT-3101 also showed a favorable safety profile across all patients.

"It has been a great privilege to work on and meaningfully progress RVT-3101, and we are convinced that Roche will be able to build on these efforts and maximize patient impact with this important program going forward. We would like to thank Pfizer for their partnership in enabling creative collaborations for the benefit of patients, and for their ongoing support. This is one of many examples of Roivant furthering its mission to accelerate the development and commercialization of medicines that matter while delivering value to patients and shareholders alike," said Matt Gline, CEO of Roivant.

Frank Torti, M.D, Chairman and CEO of Telavant and Vant Chair at Roivant, added: "We are eager to see RVT-3101 rapidly advance with Roche's resources and commitment to this program. I would like to thank everyone who played a critical role in advancing the RVT-3101 program thus far, including the Telavant team, our colleagues at Pfizer and Roivant, and the program's dedicated investigators and patients."

“We strongly believe this novel TL1A directed antibody has the transformational potential to make a significant difference for patients living with inflammatory bowel disease and potentially other diseases,” said Thomas Schinecker, CEO Roche Group. “We are excited to add this promising new therapy in development to our portfolio and to make it available to patients as quickly as possible.”

Terms of the Acquisition
Under the terms of the agreement, Roche will pay a purchase price of $7.1 billion upfront and a near-term milestone payment of $150 million. Upon closing of the transaction, Roche will have full rights to further develop and manufacture RVT-3101 and commercialize it in the US and in Japan pending clinical and regulatory success. Roche is committed to starting a global Phase 3 trial for RVT-3101 as soon as possible to bring this promising therapy to the patients suffering from inflammatory bowel disease. Outside of the US and Japan, Pfizer holds commercialization rights.

In addition, following the closing of the transaction, Roche will also have an option to enter into a global collaboration with Pfizer on a next-generation p40/ TL1A directed bispecific antibody, currently in Phase 1. Telavant was jointly formed by Roivant and Pfizer in 2022 to develop and commercialize RVT-3101 in the US and Japan. Roivant owns 75% of the issued and outstanding shares of common stock and preferred stock of Telavant and Pfizer owns the remaining 25%.

The transaction is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary closing conditions. The closing of the transaction is currently expected to take place in Q4 2023 or in Q1 2024.

Freshfields Bruckhaus Deringer LLP is acting as legal counsel for Roivant. Citi is acting as the exclusive financial advisor to Roche and Davis Polk & Wardwell LLP is acting as legal counsel to Roche.

Investor Call
A conference call and webcast will be held at 8AM ET on Monday, October 23, 2023, to discuss this transaction. To access the conference call by phone, please register online using this registration link. The presentation and webcast details will 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 RVT-3101
RVT-3101 is a potential first-in-class agent that targets both inflammatory and fibrotic pathways by inhibiting TL1A. It has been shown to modulate the severity of inflammation and fibrosis by stimulating the TH1 and TH17 pathways, in addition to activating fibroblasts. As such, RVT-3101 has the potential to provide greater efficacy by hitting multiple inflammatory and fibrotic pathways.

RVT-3101 has been evaluated in a Phase 2 study (TUSCANY) in 50 patients, and in a large global Phase 2b study (TUSCANY-2) in 245 adult participants with moderate to severe ulcerative colitis. TUSCANY-2, a large, global, randomized, double-blinded, placebo-controlled dose-ranging Phase 2b study was set up to investigate the efficacy, safety and pharmacokinetics of RVT-3101 administered monthly subcutaneously in adult patients.

Key efficacy analyses from the induction period were measured at week 14 and the maintenance (chronic) phase at week 56. Patients who received RVT-3101 in the induction period were preassigned to receive either the same or a lower dose in the maintenance (chronic) period. Roivant reported positive data for the induction period of the study in January 2023 and the chronic phase in June 2023. A Phase 2 study in Crohn's disease is ongoing.

About Inflammatory Bowel Diseases and Ulcerative Colitis
Inflammatory bowel diseases (IBD) are a group of chronic gastrointestinal disorders affecting almost 8 million people worldwide.[1] The two main types of IBD are ulcerative colitis (mainly affecting the colon and rectum) and Crohn's disease (affecting the entire gastrointestinal tract).[2,3] Patients can experience unpredictable symptoms that include abdominal pain and cramping, frequent and urgent bowel movements, diarrhea, leakage, rectal bleeding, weight loss, energy loss and fatigue.[2,3] About 80% of all individuals with IBD do not experience lasting remission, which can have a long-term impact on quality of life and leave many feeling like they have little control over their daily lives.[4]

Ulcerative colitis is most commonly diagnosed in young people aged 15 to 30 years, affecting them over the course of their entire future lives.[5] Up to a quarter of people with ulcerative colitis will require a colectomy within 10 years of diagnosis, in which all or part of the colon is removed.[6]

About Roivant
Roivant is a commercial-stage biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Today, Roivant's pipeline includes VTAMA®, a novel topical approved for the treatment of psoriasis and in development for the treatment of atopic dermatitis; batoclimab and IMVT-1402, fully human monoclonal antibodies targeting the neonatal Fc receptor ("FcRn") in development across several IgG-mediated autoimmune indications; brepocitinib, a novel TYK2/JAK1 inhibitor in late stage development for dermatomyositis, systemic lupus erythematosus, and other autoimmune conditions; and, additional 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, visit 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 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, 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 risk that the conditions to the closing of the proposed transaction may not be satisfied, (ii) the possibility that the proposed transaction may involve unexpected costs, liabilities or delays, (iii) the risk that the businesses of the companies may suffer as a result of uncertainty surrounding the proposed transaction, (iv) the risk that disruptions from the proposed transaction will harm relationships with employees, customers and suppliers and other business partners or (v) the risk that the achievement of the specified milestone described in the definitive agreement may take longer to achieve than expected or may never be achieved and the resulting contingent milestone payment 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.

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References

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4314302/pdf/10.1177_1756283X14558193.pdf
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