

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): December 1, 2022

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, \$0.000000341740141 par value per share	ROIV	The Nasdaq Global Market
Redeemable warrants, each whole warrant exercisable for one Common Share	ROIW	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 7.01. Regulation FD Disclosure.

On December 1, 2022, Roivant Sciences Ltd. (the “Company”) and Pfizer Inc. issued a press release announcing the formation of a new Vant to develop and commercialize PF-06480605 (now RVT-3101), a fully human monoclonal antibody targeting TL1A which is currently in Phase 2b development in ulcerative colitis. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The Company expects that this collaboration will not impact the Company’s previously announced cash runway into the second half of calendar year 2025. The Company expects to hold an investor call to present the clinical data and development plans for RVT-3101 at a later date.

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, or the Exchange Act, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, or the Securities Act. 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, or the SEC, 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
99.1	Roivant Sciences Ltd. Press Release, dated December 1, 2022
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: December 1, 2022

Roivant and Pfizer Form New Vant Company Focused on Developing TL1A Drug Candidate for Inflammatory and Fibrotic Diseases

- Roivant to develop PF-06480605 (now RVT-3101), a potential first in class, fully human monoclonal antibody that blocks tumor necrosis factor-like ligand 1A (TL1A), a cytokine believed to play a key role in inflammation and fibrosis
- RVT-3101 is currently being evaluated in a large global Phase 2b study (TUSCANY-2) with final results expected in 1H 2023

BASEL, Switzerland, LONDON, NEW YORK and BOSTON, December 1, 2022 (GLOBE NEWSWIRE) — Roivant Sciences (Nasdaq: ROIV) and Pfizer Inc. (NYSE: PFE) today announced formation of a new Vant to develop and commercialize PF-06480605 (now RVT-3101). RVT-3101 is a fully human monoclonal antibody targeting TL1A, which is currently in Phase 2b development in ulcerative colitis (UC). The Vant has the exclusive option to collaborate with Pfizer on a next-generation TL1A directed antibody which recently entered Phase 1.

RVT-3101 is a potential first-in-class agent that targets both inflammatory and fibrotic pathways by inhibiting TL1A, which has been shown to modulate the location and severity of inflammation and fibrosis by stimulating TH1 and TH17 pathways, in addition to activating fibroblasts. As such, RVT-3101 has the potential to provide greater efficacy by hitting multiple inflammatory pathways as well as fibrotic pathways.

RVT-3101 has been evaluated in an earlier Phase 2 study (TUSCANY) in 50 patients, and is being evaluated in a large global Phase 2b study (TUSCANY-2) in 245 adult participants with moderate to severe ulcerative colitis. The induction portion of TUSCANY-2 is complete, and the maintenance portion remains ongoing.

“Our internally discovered antibody against TL1A, could potentially be the first agent to bring biomarker-selected precision medicine to people living with inflammatory bowel disease,” said Mikael Dolsten, Pfizer’s Chief Scientific Officer, President, Worldwide Research, Development and Medical. “We are very excited about the preliminary data from the TUSCANY-2 study and for this new Vant to drive the advancement of this asset. At the same time, it enables Pfizer to bring additional innovative breakthrough medicines and vaccines to patients in need more quickly, allowing us to serve more people.”

“We believe in RVT-3101’s potential to transform the inflammatory bowel disease landscape, which has long been in need of new, innovative therapies with greater efficacy,” said Mayukh Sukhatme, President and Chief Investment Officer of Roivant. “We are excited about this collaboration with Pfizer on a potential first-in-class program, which we intend to pursue in both ulcerative colitis and in additional inflammatory and fibrotic diseases. TUSCANY-2 builds on the earlier TUSCANY data with many firsts for the class – TUSCANY-2 is the first study with subcutaneous efficacy data and the first dose-ranging study – and is among the largest Phase 2b studies ever conducted in the indication. We are encouraged by the preliminary data and look forward to presenting our data and to seeing other results from the class.”

Inflammatory bowel diseases are chronic inflammatory diseases of the gastrointestinal tract. It is estimated that up to 2 million US adults suffer from inflammatory bowel diseases, which include ulcerative colitis and Crohn’s disease. There is significant unmet treatment need for patients with inflammatory bowel disease. High rates of treatment failure mean that approximately 50% of patients are cycling off a given therapy within 6 to 12 months and are unlikely to achieve sustained remission. The commercial markets for these diseases for advanced therapies is nearly \$15 billion per year in the US alone and growing. Available treatments have very low remission rates, and thus there is a large need for an efficacious and safe therapy.

Terms of Collaboration

A new Vant or Roivant subsidiary has been created to develop and fund these programs. The Vant will be fully responsible for funding global development of RVT-3101 in UC and in additional inflammatory and fibrotic diseases and holds commercial rights in the US and Japan. Pfizer owns a 25% equity position in the Vant and maintains commercial rights outside of the US and Japan as well as representation on the company's Board of Directors.

In addition, the Vant has the exclusive option to collaborate with Pfizer on a next-generation TL1A directed antibody which recently entered Phase 1. The Vant will have the right to enter into an agreement for global development with a 50/50 cost share as well as co-commercialization rights with Pfizer prior to Phase 2 (expected in 2025).

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.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at [@Pfizer](https://twitter.com/Pfizer) and [@Pfizer News](https://twitter.com/PfizerNews), [LinkedIn](https://www.linkedin.com/company/pfizer), [YouTube](https://www.youtube.com/channel/UCv31111111111111111111) and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

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.

Pfizer Disclosure Notice

The information contained in this release is as of December 1, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about, among other things, PF-06480605 (now RVT-3101), an additional antibody asset and a collaboration between Pfizer and Roivant and a new biopharmaceutical company, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when any applications may be filed for any potential indications for PF-06480605/RVT-3101 or the additional antibody asset in any jurisdictions; whether and when regulatory authorities may approve any such applications that may be filed for PF-06480605/RVT-3101 or the additional antibody asset, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether PF-06480605/RVT-3101 or the additional antibody asset will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of PF-06480605/RVT-3101 or the additional antibody asset; whether the collaboration with Roivant will be successful; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.
