

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): September 28, 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.)

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

On September 28, 2022, the Company's subsidiary, Immunovant, Inc. ("Immunovant"), issued a press release announcing IMVT-1402, a Next Generation Anti-FcRn. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

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 8.01. Other Events.

On September 28, 2022, Immunovant will provide a corporate update regarding its business at the Company's Investor Day webcast. A copy of the presentation to be used during the webcast is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press release dated September 28, 2022.
99.2	Presentation dated September 28, 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: September 28, 2022

Immunovant Announces IMVT-1402, a Next Generation Anti-FcRn

- In animal studies, deep IgG lowering similar to batoclimab with no or minimal impact on albumin and low-density lipoprotein (LDL) was observed.
- Plan to submit IND and initiate Phase 1 study in early 2023 with initial data expected in mid-2023.
- Previously announced programs for lead asset batoclimab continue at full speed.
- Two asset anti-FcRn franchise offers multiple potential development and commercial synergies, with composition of matter patent protection expected for IMVT-1402 through at least 2042.

NEW YORK, September 28, 2022 – Immunovant, Inc.(Nasdaq: IMVT), a clinical-stage biopharmaceutical company committed to enabling normal lives for people with autoimmune diseases, today announced a new anti-FcRn, IMVT-1402, at Roivant’s Investor Day at 11:00 am on September 28, 2022. The presentation can be accessed at the Investor Relations section of the Company’s website, located at www.immunovant.com.

“We are excited to unveil IMVT-1402, which has a combination of features that we believe could make a significant impact in the lives of people with autoimmune diseases,” said Pete Salzmann, M.D., Chief Executive Officer at Immunovant. “As with batoclimab, IMVT-1402 may offer deep, potentially best-in-class IgG reduction formulated for the same simple subcutaneous route of administration delivered in a matter of seconds. Additionally, IMVT-1402 has been observed to have minimal or no impact on levels of albumin and LDL in animal studies. With these encouraging preclinical results, we are pursuing an accelerated development plan to bring IMVT-1402 to the clinic, with a Phase 1 study planned to start in early 2023 contingent on IND clearance. Importantly, our cash runway guidance into calendar year 2025 remains unchanged, as expected Phase 1 development costs for IMVT-1402, have been included,” Dr. Salzmann added.

The combined franchise of batoclimab and IMVT-1402 may enable multiple paths to enhanced value creation for Immunovant. From a development perspective, proprietary patient level data from batoclimab complements the general strength of IgG as a biomarker, and these data together may allow us to accelerate the development of IMVT 1402 from our planned Phase 1 trial directly to planned pivotal studies. IMVT-1402 may also create an expanded opportunity for Immunovant in therapeutic areas such as Rheumatology, Hematology, and others, where chronic, maximal IgG reduction may be required to deliver the most robust clinical efficacy. From a commercial standpoint, if approved, the two-asset franchise may offer a range of synergies in addition to faster cash flow from batoclimab’s potential launches. IMVT-1402 is also expected to have composition of matter patent protection through at least 2042, assuming issuance of the pending patent.

Immunovant’s previously announced programs studying batoclimab in Myasthenia Gravis, Thyroid Eye Disease, Chronic Inflammatory Demyelinating Polyneuropathy and Graves’ Disease continue at full speed. The trial design and lead asset for Warm Autoimmune Hemolytic Anemia will be determined based on an expected engagement with the FDA in calendar year 2022.

About Immunovant, Inc.

Immunovant, Inc. is a clinical-stage biopharmaceutical company dedicated to enabling normal lives for people with autoimmune diseases. As a leader in FcRn inhibitor technology, the Company is boldly developing innovative therapies for a range of debilitating autoimmune diseases with significant unmet patient needs. For additional information on the Company, please visit www.immunovant.com.

Forward Looking Statement

This press release contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as “can,” “may,” “might,” “will,” “would,” “should,” “expect,” “believe,” “estimate,” “design,” “plan,” “intend,” and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include Immunovant’s plan to complete a toxicology study in IMVT-1402 for a planned IND filing in early calendar year 2023 and to start a Phase 1 study in IMVT-1402 in the first quarter of calendar year 2023 with initial results expected in the middle of calendar year 2023, Immunovant’s plan to initiate a Phase 2b clinical trial for batoclimab in Chronic Inflammatory Demyelinating Polyneuropathy in the second half of calendar year 2022 with initial results from open-label period 1 expected in the first half of calendar year 2024; Immunovant’s plan to initiate a Phase 2 clinical trial for batoclimab in Graves’ Disease in early 2023 with initial results expected in the second half of calendar year 2023; Immunovant’s plan to report topline data from its Phase 3 trial for batoclimab in Myasthenia Gravis in the second half of calendar year 2024; Immunovant’s plan to initiate two Phase 3 clinical trials for batoclimab in Thyroid Eye Disease in the second half of calendar year 2022 with expected topline data readouts in the first half of calendar year 2025; Immunovant’s plan to finalize its trial design and compound selection in Warm Autoimmune Hemolytic Anemia following expected interactions with FDA in calendar year 2022; Immunovant’s plan to develop batoclimab and IMVT-1402 across a broad range of autoimmune indications; expectations with respect to the safety and monitoring plan and size of the safety database for these planned clinical trials; the timing of discussions with regulatory agencies; the size and growth of the potential markets for Immunovant’s product candidates and indication selections; Immunovant’s plan to explore in subsequent study periods follow-on treatment with alternative dosing regimens; Immunovant’s expectations regarding patient enrollment, timing, the design and results of clinical trials of its product candidates and indication selections; Immunovant’s beliefs regarding its cash runway, and the potential benefits of batoclimab’s and IMVT-1402’s unique product attributes; and expectations regarding the issuance of any pending patents. All forward-looking statements are based on estimates and assumptions by Immunovant’s management that, although Immunovant believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Immunovant expected. Such risks and uncertainties include, among others: initial results or other preliminary analyses or results of early clinical trials may not be predictive final trial results or of the results of later clinical trials; results of animal studies may not be predictive of results in humans; the timing and availability of data from clinical trials; the timing of discussions with regulatory agencies, as well as regulatory submissions and potential approvals; the continued development of Immunovant’s product candidate, including the timing of the commencement of additional clinical trials and resumption of current trials; Immunovant’s scientific approach, clinical trial design, indication selection and general development progress; future clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release; any product candidate that Immunovant develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; Immunovant’s pending composition of matter patent for IMVT-1402 may not be issued; Immunovant’s product candidate may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of the ongoing COVID-19 pandemic, geopolitical tensions, and adverse macroeconomic conditions on Immunovant’s clinical development plans and timelines; Immunovant’s business is heavily dependent on the successful development, regulatory approval and commercialization of batoclimab and IMVT-1402; Immunovant is at an early stage in development of for IMVT-1402 and in various stages of clinical development for batoclimab; and Immunovant will require additional capital to fund its operations and advance batoclimab and IMVT-1402 through clinical development. These and other risks and uncertainties are more fully described in Immunovant’s periodic and other reports filed with the Securities and Exchange Commission (SEC), including in the section titled “Risk Factors” in Immunovant’s most recent Annual Report on Form 10-K, its Form 10-Q filed with the SEC on August 5, 2022, and Immunovant’s subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Immunovant undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Contact:

Chau Cheng, PhD, MBA
VP Investor Relations
Immunovant, Inc.
info@immunovant.com



**Building a
Leading Franchise**
Next Generation FcRn: IMVT-1402



September 2022



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All trademarks, trade names, service marks, and copyrights appearing in this presentation are the property of their respective owners. Dates used in this presentation refer to the applicable calendar year unless otherwise noted.




Our vision:
Normal lives for people with autoimmune disease

Driven by our core values



**Love
Trailblazing**



**Bolder,
Faster**



**All
Voices**



Building a leading anti-FcRn franchise: Introducing IMVT-1402

IMVT-1402



Novel, fully human, monoclonal antibody inhibiting FcRn-mediated recycling of IgG



IMVT-1402 is the successful culmination of in-house development

Animal studies¹ have demonstrated **IMVT-1402** may have deep, potentially best-in-class IgG lowering, similar to batoclimab, and yet may have minimal impact on albumin and LDL

IMVT-1402 development can be accelerated by leveraging proprietary insights and well-known biology: IgG lowering has translated into clinical efficacy in 10+ late-stage trials², including trials with batoclimab

Phase 1 study planned to initiate in Q1 2023 with initial data expected in mid-2023

Development of **IMVT-1402** and batoclimab intended to maximize our FcRn franchise value, with potential composition of matter patent protection for IMVT-1402 to 2042+³

1. Data on file at Immunovant
2. Source: Anti-FcRn data publicly disclosed by Immunovant, Argenx, UCB, and Momenta
3. Assuming issuance of pending patent

FcRn inhibition has broad potential in autoimmune diseases: 19 announced indications¹ across multiple therapeutic areas create clinical and commercial² opportunity for a franchise approach



NEUROLOGY

Myasthenia gravis (MG)
Chronic inflammatory demyelinating polyneuropathy (CIDP)
Myositis
Autoimmune encephalitis
Myelin oligodendrocyte glycoprotein antibody disorders (MOG-antibody disorder)



ENDOCRINOLOGY

Thyroid eye disease (TED)
Graves' disease



RENAL

Membranous nephropathy
Lupus nephritis



HEMATOLOGY

Warm autoimmune hemolytic anemia
Hemolytic disease of the fetus and newborn
Idiopathic thrombocytopenic purpura



RHEUMATOLOGY

Primary Sjogrens syndrome
Systemic lupus erythematosus
Rheumatoid arthritis



DERMATOLOGY

Bullous pemphigoid
Pemphigus foliaceus
Pemphigus vulgaris
Cutaneous lupus erythematosus



1. Indications announced or in development with anti-FcRn assets by Immunovant, Argenx, JNJ, and UCB
2. If approved by regulatory authorities

Anti-FcRn market is unique in terms of breadth of potential indications and in terms of having a strong biomarker

»» IgG reduction is a well-established biomarker for degree of clinical response¹

»» Some patient populations and indications likely need **maximal IgG suppression** (up to ~80%) to maximize clinical benefit and duration of this need will vary

»» We believe broad validity of IgG as a biomarker across indications enables an **accelerated development** path for a **new anti-FcRn** particularly with proprietary patient level data on file

+ Next generation anti-FcRn: IMVT-1402



IMVT-1402 has potentially best-in-class attributes to address large unmet need in autoimmune disease

01

DEEP IgG LOWERING

Animal studies suggest deep dose-dependent IgG lowering similar to batoclimab¹

02

CONVENIENT ADMINISTRATION

Formulated for simple subcutaneous injection that may enable self-administration at home

03

FAVORABLE ANALYTE PROFILE

Animal studies support the potential for a favorable analyte profile with no or minimal effect on albumin and LDL

04

COMPELLING PATENT PROTECTION²

Pending 1402 composition of matter patent expiring 2042+

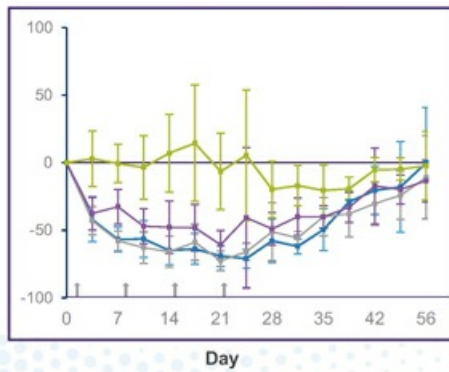


1. Data on file at Immunovant
2. Assuming issuance of pending composition of matter patent as anticipated

IMVT-1402 and batoclimab demonstrated similar, maximum IgG reduction

Head-to-Head Monkey Study

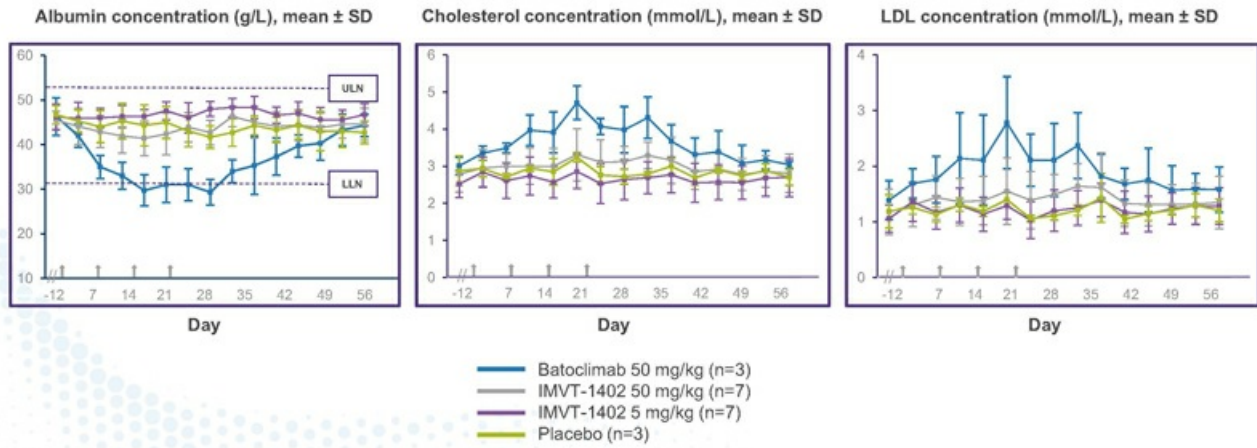
IgG concentration (mg/mL),
mean percent change from baseline \pm SD



- 20 monkeys, dosed IV in head-to-head study across four groups
- At comparable doses, IgG lowering is similar for both batoclimab and IMVT-1402
- Cynomolgus monkeys observed to be reliable pharmacodynamic proxy for anti-FcRn mediated impacts on IgG^{1,2}

IMVT-1402 and placebo demonstrated similar albumin and LDL

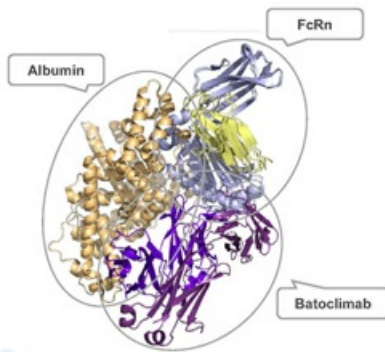
Head-to-Head Monkey Study



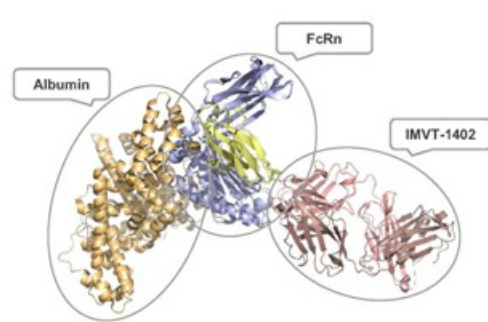
SD, standard deviation; ULN, upper limit of normal; LLN, lower limit of normal; Arrows indicate time of dosing.
Data on file at Immunovant

IMVT-1402 is designed to deliver maximum IgG reduction while minimizing interference with the albumin binding site

Batoclimab



IMVT-1402



IMVT-1402 development is well underway, with initial Phase 1 data expected in mid-2023



Novel, fully human, monoclonal antibody inhibiting FcRn-mediated recycling of IgG



1. The assumptions upon which we have based our estimates, including expenditures relating to planned or potential clinical trials, are routinely evaluated and may be subject to change
2. As of September 22, 2022, our cash balance was approximately \$410M, and our cash burn for the period from July 1, 2022 to September 22, 2022 was approximately \$17M

Anti-FcRn Franchise Strategy



Building an anti-FcRn franchise with differentiated assets to address a range of patient needs

Batoclimab



Tailored dosing to address varying symptom severity across indications and stage of disease

- Short term maximal IgG suppression
- Lower chronic doses where less IgG suppression needed
- Fixed duration dosing in certain conditions

IMVT-1402




Chronic dosing to address symptom severity and duration for extended periods of time (>12 weeks)¹

- Sustained maximal IgG suppression where needed
- Chronic delivery with simple subcutaneous delivery in seconds
- No or minimal impact to albumin / LDL

Building an anti-FcRn franchise with differentiated assets and a rational development strategy to optimize ability to address unmet need


Batoclimab



Induction and Maintenance in **MG, CIDP**
Fixed Duration in **TED**

The diagram shows a blue Y-shaped antibody structure centered within a blue circle. Six small blue plus signs are arranged around the circle, representing the binding sites of the antibody.

IMVT-1402



Sustained, maximal IgG suppression in additional therapeutic areas such as **Rheumatology** and **Hematology**

The diagram shows a yellow Y-shaped antibody structure centered within a yellow circle. Six small yellow plus signs are arranged around the circle, representing the binding sites of the antibody.

Planning to leverage data and learnings from batoclimab to accelerate development of IMVT-1402

Potential case study in Graves' Disease

Batoclimab Phase 2 trial in Graves' Disease to define effect size and trial design

IMVT-1402 dosing to be informed by parallel planned Phase 1 trial

Combine learning to initiate planned pivotal trial with IMVT-1402

Batoclimab and IMVT-1402 have the potential to offer multiple differentiated product features, if approved

		Immunovant Franchise	
Product and program attributes	efgartigimod ¹	batoclimab	IMVT-1402 ²
IgG reduction ~65%	X	X	X
IgG reduction ~80%		X	X
Albumin/LDL changes: none or minimal	X		X
Subcutaneous (SC) formulation delivered in seconds		X	X
Chronic dosing to achieve ~65%	X	X	X
Chronic dosing to achieve ~65% with SC in seconds		X	X
Chronic dosing to achieve ~80% with SC in seconds			X
Induction and maintenance dosing ³	N/A, requires high dose	MG Ph 3, CIDP	Possible
Fixed duration dosing	Possible	TED Ph 3	Possible
Chronic higher dosing (with saturating dose)	N/A, requires high dose	Not planned	Possible
As needed cyclic dosing	X	Not planned	Not planned
Key product candidate advantages favor batoclimab and IMVT-1402	1. No Albumin/LDL changes 2. Exclusive Halozyme partnership	1. Deeper IgG reduction with 680 mg 2. SC delivery in seconds	1. 680 mg-like IgG reduction 2. SC delivery in seconds 3. Minimal Albumin/LDL change



1. Source: Argenx Corporate Presentation, June 2022
 2. Potential outcomes if Phase 1 results are as predicted by pre-clinical studies in cynomolgus monkeys
 3. Induction refers to starting with saturating dose that can achieve ~80% IgG reduction

We believe franchise value is maximized by developing both batoclimab and IMVT-1402



Lead asset **batoclimab** full speed ahead in pivotal programs for **MG**, **TED** and **CIDP**



Earlier **batoclimab** launches may provide faster path to positive cash flow and enable commercial¹ synergies across the franchise



Complementary new asset **IMVT-1402** expected² to expand opportunity in additional therapeutic areas and increase the clinical and commercial potential of the combined franchise



We believe patient level data from **batoclimab** and strength of IgG as a biomarker can accelerate the development of **IMVT-1402**



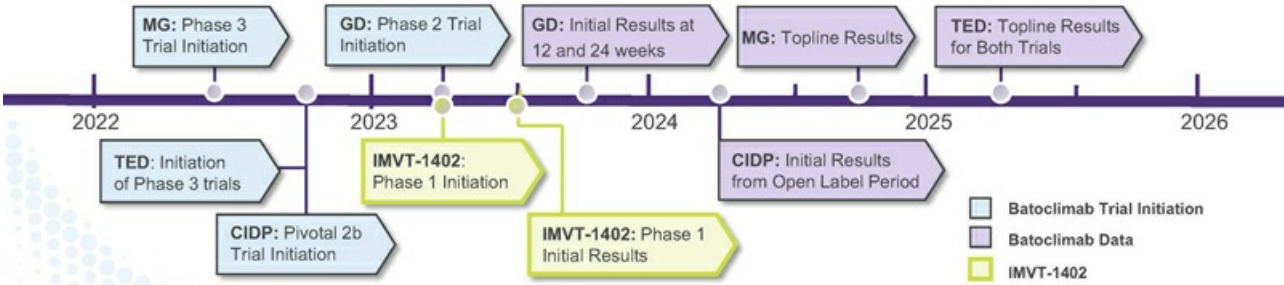
IMVT-1402 composition of matter patent protection to 2042+³

+ Summary



Multiple paths to enhanced value creation when batoclimab and IMVT-1402 are developed together

We believe franchise value is maximized in both the near and longer term¹



A leader in FcRn inhibitor technology dedicated to enabling normal lives for people with autoimmune diseases

