UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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 9, 2024

IMMUNOVANT, INC.

(Exact name of Registrant as specified in its Charter)

Delaware (State or other jurisdiction of incorporation or organization) 001-38906 (Commission File Number) 83-2771572 (IRS Employer Identification No.)

10018

(Zip Code)

320 West 37th Street New York, NY

(Address of principal executive offices)

Registrant's telephone number, including area code: (917) 580-3099

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:

Written communications 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 Stock, \$0.0001 par value per share	IMVT	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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company \Box

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 9, 2024, Immunovant, Inc. (the "Company") issued a press release providing an update on its Graves' Disease ("GD") development program. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K 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.

As described in the press release, the Company will host a conference call and webcast to discuss the results of the GD trial at 8:00 a.m. ET on September 9, 2024. A copy of the presentation to be used by the Company during the conference call is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits	
Exhibit No.	Description
99.1	Press release, dated September 9, 2024.
99.2	Presentation, dated September 9, 2024.
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.

IMMUNOVANT, INC.

By: /s/ Eva Renee Barnett

Eva Renee Barnett Chief Financial Officer

Date: September 9, 2024

Exhibit 99.1

Immunovant Provides Update on Graves' Disease Development Program

- High dose batoclimab achieved 76% response rate in patients uncontrolled on antithyroid drugs (ATDs) at week 12
- High dose batoclimab achieved 56% ATD-free response rate in patients uncontrolled on ATDs at week 12
- Strong correlation observed between degree of IgG lowering and clinical outcomes yields potential best-in-class and first-in-class opportunity for IMVT-1402 in Graves' Disease (GD)
- Real world claims data indicates 25-30% of Graves' Disease patients per year are uncontrolled on ATDs with minimal to no existing therapeutic options representing an attractive commercial opportunity with limited competition
- IND cleared with initiation of IMVT-1402 pivotal trial in GD expected by calendar year end

NEW YORK, September 9, 2024 -- Immunovant, Inc. (Nasdaq: IMVT), a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases, today reported positive results from the Phase 2a trial of batoclimab in Graves' Disease. Immunovant also disclosed data from several proprietary market research studies that showed a consistent unmet need among ATD treated patients who are intolerant to, uncontrolled on or relapsed after ATDs. Finally, Immunovant also announced alignment with the U.S. Food & Drug Administration (FDA) and Investigational New Drug Application (IND) clearance with initiation of a pivotal trial of IMVT-1402 in GD expected by December 31, 2024.

As previously disclosed, the batoclimab phase 2a trial in uncontrolled GD enrolled patients who were hyperthyroid despite ATD therapy. Participants in the trial received 12 weeks of high dose batoclimab, 680 mg weekly by subcutaneous injection (SC) followed by 12 weeks of lower dose batoclimab, 340 mg weekly SC. At the end of the first 12 weeks, participants experienced a mean IgG reduction of 77% leading to a 76% Response rate (defined as T3 and T4 falling below the upper limit of normal (ULN) without increasing the ATD dose). In addition, by the end of 12 weeks of higher dose batoclimab, 56% achieved an ATD-Free Response (defined as T3 and T4 falling below the ULN and the patient simultaneously tapering completely off their ATD). Despite benefiting from a lower starting IgG level after 12 weeks of 680mg therapy, during Weeks 13 to 24, the lower 340mg dose of batoclimab resulted in mean IgG reduction of 65% (vs. 77% on 680mg dose) with a correspondingly lower responder rate of 68%. In addition, a lower ATD-Free Response rate of 36% was also observed in the second 12 weeks. Finally, patients who achieved at least a 70% IgG reduction at the end of the trial had nearly a threefold higher ATD-Free Response rate than those who did not (60% vs. 23%).

"We are thrilled to share these updates today which we believe validate a large and important degree of unmet medical need in patients uncontrolled on ATDs and which we believe

demonstrate strong response rates in this same population," said Pete Salzmann, M.D., chief executive officer of Immunovant. "We find the correlation between clinical response and IgG lowering impressive and believe this creates not only a potential first-in-class but also a potential best-in-class opportunity for IMVT-1402. We are very pleased to have aligned with the FDA on a pivotal trial design that we expect to initiate by the end of the year."

Webcast Details

Immunovant will host a webcast at 8:00 a.m. ET today to discuss these updates. Please click here to register for the event. The live webcast will also be available under the News & Events section of Immunovant's website. A replay of the event and presentation will be available immediately following the event.

About Immunovant, Inc.

Immunovant, Inc. is a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases. As a trailblazer in anti-FcRn technology, the Company is developing innovative, targeted therapies to meet the complex and variable needs of people with autoimmune diseases. For additional information on the Company, please visit immunovant.com.

Forward-Looking Statements

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," "anticipate," "intend," and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include, but are not limited to, statements regarding the potential benefits of IMVT-1402's unique product attributes and potential first-in-class and best-in-class profile; the expected initiation of a pivotal trial of IMVT-1402 in GD and the timing thereof; and the potential commercial opportunity of IMVT-1402 as a treatment for GD. 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: Immunovant may not be able to protect or enforce its intellectual property rights; initial results or other preliminary analyses or results of early clinical trials may not be predictive of final trial results or of the results of later clinical trials; 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 candidates, including the number and timing of the commencement of additional clinical 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 product candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of macroeconomic and geopolitical factors on Immunovant's business operations and supply chain, including its clinical

development plans and timelines; Immunovant's business is heavily dependent on the successful development, regulatory approval, and commercialization of IMVT-1402 and/or batoclimab; Immunovant is at various stages of clinical development for IMVT-1402 and batoclimab; and Immunovant will require additional capital to fund its operations and advance IMVT-1402 and batoclimab 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 Form 10-Q filed with the SEC on August 6, 2024, 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.

Investor Contact:

Renee Barnett, MBA Chief Financial Officer Immunovant, Inc. info@immunovant.com



Targeted science, + Tailored solutions +

for people with autoimmune disease

Graves' Disease Program Update September 9, 2024



Forward-Looking Statements

This presentation 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 the timing and results of Immunovant's clinical trials of IMVT-1402 and batoclimab, including data from the Phase 2a clinical trial of batoclimab in Graves' Disease; 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 including the estimated market opportunity in Graves' Disease; Immunovant's plan for a pivotal trial of IMVT-1402 in Graves' Disease; and Immunovant's beliefs regarding the potential benefits of IMVT-1402's unique product attributes. 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 of 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 development of Immunovant's product candidates, 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 presentation; 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 product candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the effect of global factors such as geopolitical tensions and adverse macroeconomic conditions on Immunovant's business operations and supply chains, including its 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 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 Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2024, filed with the SEC on August 6, 2024, 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.

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.



Proof of concept achieved in Graves' Disease, positioning IMVT-1402 to potentially be best-in-class and first-in-class



>50% of Patients are ATD-Free Responders: 56% of patients not only achieved normal T3 and T4 levels but also ceased ATD therapy entirely by 12 weeks

Lower is Better: Deeper IgG reductions drove meaningfully higher response rates, positioning IMVT-1402 to potentially be best-in-class

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High Unmet Need Yields Attractive Commercial Opportunity: 25-30% of Graves' Disease patients per year are uncontrolled on / intolerant to ATDs with no pharmacologic options

IMVT-1402 IND Cleared: Received FDA greenlight, enabling straight to pivotal transition





Graves' Disease is a classic autoimmune condition driven by the presence of thyroid stimulating antibodies



Graves' Disease: high patient burden and significant morbidity



Minimal innovation in Graves' Disease treatment options over the past 70+ years

No existing pharmacologic therapy addresses underlying disease pathology

Standard-of-Care Treatments	Associated Challenges
Anti-Thyroid Drugs (ATDs) (e.g., Methimazole, Propylthiouracil)	 ~25-30% of patients are relapsed, uncontrolled or intolerant to ATDs¹ Potential for serious adverse events, including hepatotoxicity (liver injury ~3%) and agranulocytosis (loss of white blood cells ~0.3%)^{2,3}
Radioactive lodine	 TED development and/or exacerbation in 15-33% of patients⁴ Dose dependent, long-term increased risk of death (5-12% increased risk per 100-mGy dose) from solid cancers⁵ Necessitates life-long thyroid replacement therapy
Thyroidectomy	 Recurrent laryngeal nerve damage risk in 1-4% of patients leading to dysphonia³ Permanent hypoparathyroidism observed in 2.6% of patients⁴ Necessitates life-long thyroid replacement therapy
MIMMUNOVANT*	Sources: 1. Roivant / Inovalon Claims Analysis – 2021 incident patient population, first-line treatment is primary treatment in the first-year post diagnosis, claims review included a five-year lookback to define the incident population, IMVT Market Research 2020-2023; 2. Suzuki, N., et al. (2019), 3. Smith, T., & Hegedüs, L. (2016). 4. Sundaresh, V., et al. (2013). 5. Kitahara, C., et al. (2019).

In North America, the treatment paradigm for Graves' Disease continues to shift away from radioactive iodine and surgery



Shift away from ablation and lack of new medical therapies leaves 25-30% of patients who are relapsed, uncontrolled, or intolerant to ATDs





Goals for the Graves' Disease Phase 2 Program



Graves' Disease Phase 2 study design tests two doses of batoclimab

12 weeks of 680mg followed by 12 weeks of 340mg in Graves' Disease patients uncontrolled on ATDs



The trial population was representative of an uncontrolled population, despite ATD use

	Batoclimab SC QW
	N = 25 Mean unless otherwise noted
Age, years	47.4
Sex, % female	80%
Race, % white	92%
BMI, kg/m ²	25.4
Median time since diagnosis, months	15.7
Baseline FT3, pmol/L (ULN=6.8 pmol/L)	15.4
Baseline FT4, pmol/L (ULN=22 pmol/L)	33.9
Baseline TRAb, IU/L (ULN=1.75 IU/L)	18.0

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Batoclimab demonstrated potentially transformational results in ATD uncontrolled patients with greater response driven by higher IgG lowering





>50% of patients receiving high-dose batoclimab not only achieved normal T3 and T4 levels but also ceased ATD entirely by 12 weeks





Deeper IgG reduction at 24 weeks was associated with a meaningfully higher ATD-free responder rate





High-dose batoclimab drives rapid normalization of T3 and T4 and ATD tapering



Batoclimab was well-tolerated with no new safety signals identified

	Batoclimab SC QW
	N = 25 n (%)
Patients with any TEAE	25 (100)
Patients with any Serious TEAE	1 (4)
Patients with any Treatment-related Serious TEAE	0
Patients with any Treatment-related TEAE Leading to Study Drug Withdrawal	0
Patients with any TEAE Leading to Study Drug Dose Reduction or Interruption ¹	1 (4)
Patients with any TEAE Leading to Study Discontinuation ²	1 (4)
Deaths	0

All treatment-related TEAEs were mild or moderate with no serious treatment-related TEAEs reported

19 Notes: 1) Patient experienced moderate menstrual disorder that led to a missed dose. Patient resumed treatment the following week and completed 24 weeks of batoclimab treatment; 2) Patient underwent cholecystectomy due to pre-existing gallstones. Event was not related to study treatment.



First pivotal trial for IMVT-1402 in Graves' Disease





Multiple market-sizing analyses confirm high unmet need in Graves' Disease with at least 25-30% of patients relapsed, uncontrolled, or intolerant to ATDs



Analysis #1: Real world claims analysis indicates a substantial untapped opportunity in the prevalent treated Graves' Disease market



Analysis #2: Real world claims analysis conservatively estimates an incident US population of ~65K leading to an annual second line market of ~20K patients



Analysis #3: Surveyed endocrinologists indicate that ~25% of their patients remain uncontrolled on ATDs

Endocrinologist Survey Methodology

- Board-certified endocrinologists (N=140) were screened based on Graves' Disease patient volume (10+ patients in the past 3 months) and time in practice (2-40 years in practice with ≥50% of time spent in direct patient care)
- 2. The N=140 endocrinologists completed a doubleblinded online quantitative survey regarding their treatment experience

Graves' Disease Patient Types: HCP Survey (n=140 HCPs, % of patients) 22% Uncontrolled on ATDs 25% Relapsed or uncontrolled while off ATD treatment 35% Achieved durable euthyroid status

18%

off ATD treatment

Underwent definitive

treatment Other

IMMUNOVANT[®] Sources: 1) Graves' Disease Physician Survey (n=140) by Immunovant

Analysis #4: Real-world in-depth chart review of 1,000+ patient records from 140 endocrinologists indicates ~25% have never achieved euthyroid status on ATDs

Real World Chart Audit Methodology

- As part of the endocrinologist survey, each healthcare provider was asked to complete N=8 Graves' Disease patient charts for a total of 1,120 charts collected via randomized selection to minimize bias
- 2. Chart selection followed various qualifications:
 - 1. Diagnosed with Graves' Disease
 - 2. Seen by the healthcare provider in the past 3 months
 - 3. Under the healthcare provider's care for at least 6 months
 - 4. First visit in the past 3 years
 - 5. Either on ATD therapy currently or previously



IMMUNOVANT[®] *Excludes patients who have received definitive treatment; Sources: Patient Chart Audit analysis (n=988 on ATD, n=1120 total) by Immunovant

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Analysis #5: ~35% of Graves' Disease patients report that they have found it difficult or very difficult to achieve stable thyroid disease while on ATDs

Patient Survey Methodology

- A double-blinded online survey was conducted with N=100 patients who reported being diagnosed by a healthcare provider with Graves' Disease
- Screening criteria included patients who were diagnosed in the past 3 years OR diagnosed in the past 5 years with a recurrence in the past year
- 3. Excluded patients who had received radioactive iodine or thyroidectomy



IMMUNOVANT[®] Sources: Graves' Disease Patient Quantitative Survey (n=100) by Immunovant



Tepezza®'s fast ramp in a TED market dominated by generics and procedures illustrates the potential of IMVT-1402 in Graves' Disease



Within two years post-launch, Tepezza saw rapid adoption, taking a 20% market share and generating ~\$2B net sales in a
market dominated by generic steroids and procedures, despite risk of hearing loss

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Notes: Dollars reported in millions. Sources: Horizon Therapeutics PLC 10-K documents, Inovalon TED Claims Analysis 2019, 2022, Morgan Stanley Global Healthcare Conference Sept 2022, Horizon Therapeutics PLC; Launch year for Tepezza = 2020. Information presented on this slide is for illustration purposes only. Tepezza's results and past performance in the TED market may not be indicative of, and are not an estimate, forecast, guarantee, or projection of Immunovant's future results.

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IMVT-1402 is potentially best and first-in-class in Graves' Disease

