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): December 30, 2021

IMMUNOVANT, INC.
(Exact name of Registrant as specified in its Charter)

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

320 West 37th Street	
New York, NY	**10018**
(Address of principal executive offices)	**(Zip Code)**

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 ☐

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 30, 2021, Immunovant, Inc. issued a press release that it achieved alignment with the FDA Division of Neurology 1 to move forward in myasthenia gravis ("MG"). Immunovant plans to start its Phase 3 study for batoclimab in MG in the first half of calendar year 2022. 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, 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 Immunovant, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated December 30, 2021.
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: December 30, 2021

Exhibit 99.1

Immunovant Provides Regulatory Update Regarding Initiation of Phase 3 Trial for Batoclimab in Myasthenia Gravis in the First Half of 2022

NEW YORK, December 30, 2021 (GLOBE NEWSWIRE) -- Immunovant, Inc. (Nasdaq: IMVT), a clinical-stage biopharmaceutical company focused on enabling normal lives for people with autoimmune diseases, announced that the Company achieved alignment with the FDA Division of Neurology 1 ("FDA") to move forward in myasthenia gravis ("MG"). Immunovant plans to start its Phase 3 study for batoclimab in MG in the first half of calendar year 2022.

The trial will include an induction (primary efficacy) period during which Immunovant plans to study doses of 680mg and 340mg of batoclimab delivered weekly by subcutaneous injection. The primary efficacy analysis will be based on MG-ADL measured in Acetylcholine Receptor Antibody Positive subjects through 12 weeks of blinded, placebo-controlled therapy. Follow-on treatment with alternative dosing regimens (including potential lower maintenance and higher rescue doses) will be explored in subsequent study periods. The safety and monitoring plan and size of the safety database are expected to be in accordance with FDA guidance and generally consistent with those being used in other similar programs. Details of the clinical trial will be presented in an upcoming investor call described below.

"We believe we have a differentiating approach to studying batoclimab in myasthenia gravis," commented Bill Macias, M.D., Chief Medical Officer. "Specifically, by applying an induction and maintenance paradigm, we aspire to develop the first anti-FcRn with flexible dosing. This approach has the potential to maximize the benefits of batoclimab's unique product attributes," Dr. Macias added.

"Based on our market research, we believe that people living with myasthenia gravis desire to achieve significant clinical improvement and want to maintain this improvement without experiencing disease flares" stated Pete Salzmann, M.D., Chief Executive Officer. "Our Phase 3 trial was designed around these insights and is intended to take advantage of batoclimab's broad therapeutic window and a simple subcutaneous delivery device to provide a patient-friendly dosing experience," continued Salzmann. This pivotal trial is on track to begin in 1H 2022 with a likely data readout in 2024. More details will be provided in an investor call on January 5th, 2022.

Conference Call Information

Immunovant will host a conference call and audio webcast on Wednesday, January 5th, 2022 at 8 a.m. ET. Following prepared remarks, the call will include a live question-and-answer session for the investment community. To access the webcast and the presentation being shared on the call, please visit Immunovant's website at https://www.immunovant.com/investors/news-events.

Participants may also dial in using the numbers provided below:
Toll Free: 1-877-407-9039
Toll/International: 1-201-689-8470

An archived webcast recording will be available on Immunovant's website for a limited time.

About Immunovant, Inc.

Immunovant, Inc. is a clinical-stage biopharmaceutical company focused on enabling normal lives for people with autoimmune diseases. Immunovant is developing IMVT-1401 ("batoclimab"), a novel, fully human anti-FcRn monoclonal antibody, as a subcutaneous injection for the treatment of autoimmune diseases mediated by pathogenic IgG antibodies.

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 “may,” “might,” “will,” “would,” “should,” “expect,” “believe,” “estimate,” and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include Immunovant’s plan to start a Phase 3 study for batoclimab in MG in the first half of calendar year 2022 with a likely data readout in 2024, and expectations with respect to the safety and monitoring plan and size of the safety database; Immunovant’s plan to explore in subsequent study periods follow-on treatment with alternative dosing regimens; Immunovant’s plan to develop batoclimab across a broad range of autoimmune indications; and the potential benefits of batoclimab’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 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 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 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 on Immunovant’s clinical development plans and timelines; Immunovant’s business is heavily dependent on the successful development, regulatory approval and commercialization of its sole product candidate, batoclimab; Immunovant is at an early stage in development of batoclimab; and Immunovant will require additional capital to fund its operations and advance 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 most recent Annual Report on Form 10-K, its Form 10-Q filed with the SEC on November 5, 2021, 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.

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