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): August 31, 2022

ImmunoGen, Inc.

(Exact name of registrant as specified in its charter)

Massachusetts	**0-17999**	**04-2726691**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

830 Winter Street, Waltham, MA 02451
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (781) 895-0600

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 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**	**Name of Each Exchange on Which Registered**
Common Stock, $.01 par value	IMGN	Nasdaq Global Select Market

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 August 31, 2022, ImmunoGen, Inc. (the "Company") issued a press release regarding its pivotal pivekimab sunirine program in blastic plasmacytoid dendritic cell neoplasm. A copy of this press release is attached as Exhibit 99.1.

The information contained in this item, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

As stated in the announcement referenced in Item 7.01 above, following a Type B meeting with the U.S. Food and Drug Administration regarding the CADENZA study, the Company now expects top-line data from the CADENZA study in 2024.

Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements, including those related to the Company's expectations for the timing of top-line data from the CADENZA study. Various factors could cause the Company's actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this Current Report on Form 8-K. Factors that could cause future results to differ materially from such expectations include, but are not limited to: the timing and outcome of the Company's preclinical and clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense, and results of preclinical studies, clinical trials, and regulatory processes; the timing and outcome of the Company's interactions with regulatory authorities; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and the resulting impact on the Company's industry and business; and other factors as set forth in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2022, the Company's Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission on May 6, 2022 and August 1, 2022, and other reports filed with the Securities and Exchange Commission. The forward-looking statement speak only as of the date of this Current Report in Form 8-K. The Company undertakes no obligation to update any forward-looking statement, whether as a result of new information, future developments, or otherwise, except as may be required by applicable law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of ImmunoGen, Inc. dated August 31, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL (eXtensible Business Reporting Language) document)

SIGNATURE

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.

ImmunoGen, Inc.

Date: August 31, 2022

/s/ Renee Lentini

Renee Lentini
Vice President and Chief Accounting Officer

Exhibit 99.1

ImmunoGen Provides Update on Pivotal CADENZA Study of Pivekimab Sunirine in Frontline Blastic Plasmacytoid Dendritic Cell Neoplasm

Review of Data from First 10 Patients Demonstrates Significant Activity and Favorable Tolerability in Both De Novo BPDCN Patients and Those with a Prior or Concomitant Hematologic Malignancy (PCHM)

Following Discussion with FDA, CADENZA Patients to be Segmented into De Novo and PCHM BPDCN Patients; Aligned with FDA on Efficacy Analysis in De Novo Patients

Additional De Novo Patients to be Enrolled with Top-line Data Expected in 2024

Continuing to Enroll Patients with PCHM to Further Explore the Potential Benefit of Pivekimab in this Population

Conference Call to be Held at 8:00 a.m. ET Today

Waltham, MA – August 31, 2022 – ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today provided an update on the pivotal Phase 2 CADENZA study of pivekimab sunirine (pivekimab) in blastic plasmacytoid dendritic cell neoplasm (BPDCN).

The CADENZA study is enrolling frontline BPDCN patients, including patients with de novo disease and those with a prior or concomitant hematologic malignancy (PCHM). Although complete responses have been observed in BPDCN patients who present with PCHM, most will not achieve full hematologic recovery due to the impact of their prior or concomitant malignancy. For these patients, achieving a complete response with partial hematological recovery (CRh) is a potentially important measure of clinical benefit.

In data from the first ten patients in the pivotal CADENZA frontline cohort, the Company observed:

- 2 of 4 de novo patients achieved CR (complete response)/CRc (clinical complete response); and
- 4 of 6 PCHM patients achieved CR/CRc/CRh.

In addition, in three frontline patients (2 de novo, 1 PCHM) enrolled prior to the opening of the pivotal cohort, all three patients achieved CR/CRc.

In conjunction with a recent Type B meeting regarding these initial data from the CADENZA study, the Company has aligned with FDA that the efficacy analysis will be conducted in de novo BPDCN patients with CR/CRc as the primary endpoint and the key secondary endpoint of duration of CR/CRc. The Company will also continue to enroll PCHM patients in CADENZA to further explore the potential benefits of pivekimab in this population. Based upon this guidance from FDA, the Company will enroll up to 20 de novo patients for purposes of the efficacy analysis. To date, a total of 6 de novo BPDCN patients have enrolled in CADENZA. Given this is an ultra-rare disease, the Company now expects to report top-line data on the primary and key secondary endpoints in 2024.

“We believe these initial frontline data from the CADENZA study further support the potential of pivekimab as an important treatment option for patients with BPDCN,” said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. “With Breakthrough Therapy designation, we have had productive discussions with FDA. Based on the initial frontline data observed to date, we will continue to explore the benefit of pivekimab in both de novo and PCHM patients. We look forward to sharing additional details of pivekimab in frontline BPDCN at an upcoming medical meeting.”

"With limited treatment options for this rare and aggressive cancer, I am encouraged by the data generated thus far for pivekimab in frontline BPDCN," said Kendra Sweet, MD, Associate Member in the Department of Malignant Hematology at Moffitt Cancer Center. "BPDCN patients with PCHM are increasingly recognized as having significant unmet need as there are no therapies specific for this population. BPDCN patients with PCHM are most likely to die of the aggressive BPDCN component, which requires urgent treatment, while the second malignancy is typically chronic and may not even require treatment. What has been observed is that patients with PCHM who've cleared their marrow of BPDCN with pivekimab may not fully recover counts, likely due to the underlying concurrent heme malignancy. Despite partial count recovery, complete clearance of BPDCN allows these patients to bridge to transplant, when eligible, the only curative option for BPDCN."

CONFERENCE CALL INFORMATION

ImmunoGen will hold a conference call today at 8:00 a.m. ET to discuss these results. To access the live call by phone, please register here. A dial-in and unique PIN will be provided to join the call. The call may also be accessed through the Investors and Media section of the Company's website, www.immunogen.com. Following the call, a replay will be available at the same location.

ABOUT PIVEKIMAB SUNIRINE

Pivekimab sunirine is a CD123-targeting ADC in clinical development for hematological malignancies, including blastic plasmacytoid dendritic cell neoplasm (BPDCN), acute myeloid leukemia (AML), and other CD123+ hematologic malignancies. Pivekimab is currently being evaluated as monotherapy for patients with BPDCN in combination with Vidaza® (azacitidine) and Venclexta® (venetoclax) for patients with untreated and relapsed/refractory AML. Pivekimab uses one of ImmunoGen's novel indolinobenzodiazepine (IGN) payloads, which alkylate DNA and cause single strand breaks without crosslinking. IGNs are designed to have high potency against tumor cells, while demonstrating less toxicity to normal marrow progenitors than other DNA-targeting payloads. The European Medicines Agency (EMA) granted orphan drug designation to pivekimab for the treatment of BPDCN in June 2020. Pivekimab also holds this designation in the U.S. In October 2020, the FDA granted pivekimab Breakthrough Therapy designation in relapsed/refractory BPDCN.

ABOUT BLASTIC PLASMACYTOID DENDRITIC CELL NEOPLASM (BPDCN)

BPDCN is a rare form of blood cancer that has features of both leukemia and lymphoma, with characteristic skin lesions, lymph node involvement, and frequent spread to the bone marrow. This aggressive cancer requires intense treatment often followed by stem cell transplant. Despite the approval of a CD123-targeting therapy, the unmet need remains high for patients, both in the frontline and in the relapsed/refractory setting.

ABOUT IMMUNOGEN

ImmunoGen is developing the next generation of antibody-drug conjugates (ADCs) to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer our patients more good days. We call this our commitment to TARGET A BETTER NOW™.

Learn more about who we are, what we do, and how we do it at www.immunogen.com.

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FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. These statements include, but are not limited to, ImmunoGen's expectations related to: the occurrence, timing, and outcome of potential preclinical, clinical, and regulatory events related to, and the potential benefits of, the Company's product candidates, including, but not limited to the enrollment of patients in the CADENZA study and the potential full approval of pivekimab sunirine in BPDCN; the timing and presentation of preclinical and clinical data on the Company's product candidates, including top-line data from the CADENZA study; and the Company's business and product development strategies. Various factors could cause ImmunoGen's actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this release. Factors that could cause future results to differ materially from such expectations include, but are not limited to: the timing and outcome of the Company's preclinical and clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense, and results of preclinical studies, clinical trials, and regulatory processes; the timing and outcome of the Company's interactions with regulatory authorities; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and the resulting impact on ImmunoGen's industry and business; and other factors as set forth in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2022, the Company's Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission on May 6, 2022 and August 1, 2022, and other reports filed with the Securities and Exchange Commission. The forward-looking statements in this press release speak only as of the date of this press release. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments, or otherwise, except as may be required by applicable law.

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