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): May 20, 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 May 23, 2022, ImmunoGen, Inc. (the "Company") issued a press release announcing the US Food and Drug Administration's (the "FDA") acceptance of the Company's Biologics License Application ("BLA") for mirvetuximab soravtansine, as further described below in Item 8.01 of this Current Report on Form 8-K.

The information contained in this item, including Item 99.1 attached here, 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.

On May 20, 2022, the FDA accepted and filed the Company's BLA for mirvetuximab soravtansine monotherapy in patients with folate receptor alpha (FRα)-high platinum-resistant ovarian cancer who have been previously treated with 1 to 3 prior systemic treatments. The application has been granted Priority Review designation and the FDA has set a Prescription Drug User Fee Act action date of November 28, 2022.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of ImmunoGen, Inc. dated May 23, 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: May 23, 2022

/s/ Renee Lentini

Renee Lentini
Vice President and Chief Accounting Officer

Exhibit 99.1

ImmunoGen Announces Acceptance of Biologics License Application for Mirvetuximab Soravtansine in Ovarian Cancer by US Food and Drug Administration with Priority Review

PDUFA Date is November 28, 2022

Waltham, MA – May 23, 2022 – ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that the US Food and Drug Administration (FDA) has accepted and filed the Biologics License Application (BLA) for mirvetuximab soravtansine monotherapy in patients with folate receptor alpha (FRα)-high platinum-resistant ovarian cancer who have been previously treated with 1 to 3 prior systemic treatments. The application has been granted Priority Review designation and FDA has set a Prescription Drug User Fee Act (PDUFA) action date of November 28, 2022.

"FDA's acceptance of our BLA under Priority Review reinforces our belief in the potential for mirvetuximab soravtansine to serve as a new standard of care for patients with FRα-high platinum-resistant ovarian cancer," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "We are pleased to be one step closer to realizing the promise of our technology and are working closely with FDA to support the evaluation of our application. We are moving quickly to build out the commercial and medical infrastructure required for a successful launch and look forward to the prospect of delivering mirvetuximab soravtansine to patients later this year."

Priority Review designation is granted to applications for therapies that may offer significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications and shortens the FDA review period to six months following acceptance.

The BLA seeks approval of mirvetuximab soravtansine under the FDA's accelerated approval pathway, which was instituted to allow for expedited development of drugs that treat serious conditions and provide a meaningful advantage over available therapies based on a surrogate endpoint and is based on results from the pivotal Phase 3 SORAYA trial. Top-line data from SORAYA were announced in November 2021 and full data from the study were presented at the Society of Gynecologic Oncology (SGO) 2022 Annual Meeting. ImmunoGen continues to enroll patients in the confirmatory MIRASOL trial, which is intended to convert the potential accelerated approval to full approval, and expects to announce top-line data from this study in early 2023.

ABOUT MIRVETUXIMAB SORAVTANSINE

Mirvetuximab soravtansine (IMGN853) is a first-in-class ADC comprising a folate receptor alpha-binding antibody, cleavable linker, and the maytansinoid payload DM4, a potent tubulin-targeting agent, to kill the targeted cancer cells.

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.

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 clinical and regulatory events related to the Company's product candidates, including the review of the Company's BLA to the FDA for mirvetuximab and full approval of mirvetuximab; the commercial launch of mirvetuximab and the potential of mirvetuximab to serve as a new standard of care for patients with platinum-resistant ovarian cancer; and the presentation of preclinical and clinical data on the Company's product candidates, including top-line data from the MIRASOL trial in early 2023. 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 Company's ability to financially support its product programs; the timing and outcome of the Company's anticipated 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, and other reports filed with the Securities and Exchange Commission.

INVESTOR RELATIONS AND MEDIA CONTACTS

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