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 3, 2023

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 3, 2023, ImmunoGen, Inc. (the "Company") issued a press release relating to the top-line results from the Company's MIRASOL trial evaluating the safety and efficacy of ELAHERE® (mirvetuximab soravtansine-gynx) compared to chemotherapy in patients with folate receptor alpha (FRα)-positive platinum-resistant ovarian cancer who have received one to three prior lines of therapy. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of ImmunoGen, Inc. dated May 3, 2023
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 3, 2023

/s/ Renee Lentini
Renee Lentini
Vice President, Interim Chief Financial Officer, and Chief Accounting Officer

Exhibit 99.1

ELAHERE® Demonstrates Overall Survival Benefit in the Phase 3 MIRASOL Trial in Patients with FRα-Positive Platinum-Resistant Ovarian Cancer

Results Show Statistically Significant Improvements in PFS, ORR, and OS Compared to Chemotherapy

First Medicine to Demonstrate an Overall Survival Advantage in Platinum-Resistant Ovarian Cancer

Submission of MAA in Europe and sBLA in US Anticipated in H2 2023

Conference Call to be Held at 8:00 AM ET Today

Waltham, MA – May 3, 2023 – ImmunoGen Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced positive top-line data from the Phase 3 confirmatory MIRASOL trial (GOG 3045/ENGOT OV-55) evaluating the safety and efficacy of ELAHERE® (mirvetuximab soravtansine-gynx) compared to chemotherapy in patients with folate receptor alpha (FRα)-positive platinum-resistant ovarian cancer who have received one to three prior lines of therapy. Based on these data, the Company plans to submit a Marketing Authorization Application (MAA) in Europe and a supplemental Biologics License Application (sBLA) in the US for the conversion to a regular approval of ELAHERE.

"I believe the data from the confirmatory MIRASOL trial are practice-changing. They demonstrate ELAHERE's superiority to chemotherapy based on all efficacy endpoints, in particular overall survival, and build on the clinical benefit of ELAHERE previously reported in the SORAYA trial," said Kathleen Moore, Associate Director of Clinical Research and Director of the Oklahoma TSET/Sarah Cannon Phase I Program, Professor of the Section of Gynecologic Oncology at The University of Oklahoma and MIRASOL Principal Investigator. "Last year's accelerated approval of ELAHERE was a paradigm-shifting development in the treatment landscape for this disease and I am confident that, with the MIRASOL data, ELAHERE has the potential to become the new standard of care for patients with FRα-positive, platinum-resistant ovarian cancer. FRα status is a 'must know' for all ovarian cancer patients and, for those with platinum-resistant disease who test positive, I believe ELAHERE should be their first treatment option."

MIRASOL (NCT04209855) is a randomized Phase 3 trial of ELAHERE versus investigator's choice (IC) of single-agent chemotherapy (weekly paclitaxel, pegylated liposomal doxorubicin, or topotecan). Eligibility criteria include patients with platinum-resistant ovarian cancer whose tumors express high levels of FRα, using the Ventana FOLR1 Assay, and who have been treated with up to three prior regimens. The primary endpoint of this trial is progression-free survival (PFS) by investigator assessment. Key secondary endpoints include objective response rate (ORR) and overall survival (OS).

Key Findings from MIRASOL
MIRASOL enrolled 453 patients; 14% had one prior line of therapy, 39% had two prior lines of therapy, and 47% had three prior lines of therapy. 62% of patients received prior bevacizumab; 55% received a prior PARP inhibitor. As of the data cutoff on March 6, 2023, the median follow-up time for OS was 13.1 months; 14% of patients on the ELAHERE arm remained on study drug compared to 3% on the IC chemotherapy arm.

- ELAHERE demonstrated a statistically significant and clinically meaningful improvement in OS compared to IC chemotherapy. With 204 OS events reported as of March 6, 2023, the median OS was 16.46 months in the ELAHERE arm, compared to 12.75 months in the IC chemotherapy arm, with a hazard ratio (HR) of 0.67, p=0.0046. This represents a 33% reduction in the risk of death in the ELAHERE arm in comparison to the IC chemotherapy arm.

- ELAHERE demonstrated a statistically significant and clinically meaningful improvement in PFS by investigator assessment compared to IC chemotherapy, with a hazard ratio of 0.65 ($p<0.0001$), which represents a 35% reduction in the risk of tumor progression or death in the ELAHERE arm compared to the IC chemotherapy arm. The median PFS in the ELAHERE arm was 5.62 months, compared to 3.98 months in the IC chemotherapy arm.
- ORR by investigator assessment in the ELAHERE arm was 42.3%, including 12 complete responses (CRs), compared to 15.9%, with no CRs, in the IC chemotherapy arm.
- PFS and ORR results by blinded independent central review were concordant with investigator assessment.
- The safety profile of ELAHERE continues to consist predominantly of low-grade ocular and gastrointestinal events. No new safety signals were identified. Compared with IC chemotherapy, ELAHERE was associated with lower rates of:
    - Grade 3 or greater treatment-emergent adverse events (TEAEs) (42% vs 54%);
    - Serious adverse events (24% vs 33%); and
    - TEAEs leading to discontinuation of study drug (9% vs 16%).

"We are elated with the positive top-line results from MIRASOL. We believe the impressive efficacy data and consistent safety data reinforce ELAHERE's benefit for patients with platinum-resistant ovarian cancer," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "Importantly, ELAHERE is the first drug to show an overall survival benefit in this patient population. These results are remarkable and we extend our appreciation to all of the patients and physicians who participated in MIRASOL. We look forward to presenting full data from the trial at a medical meeting later this year."

"These MIRASOL data show ELAHERE is a first-in-class, biomarker-driven ADC for the treatment of FRα-positive platinum-resistant ovarian cancer and mark a significant milestone for patients and our organization," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "We believe these data will provide the foundation for pursuing a marketing authorization in Europe and elsewhere, and seeking full approval in the US, support our goal of delivering ELAHERE to FRα-positive patients worldwide, and reinforce our conviction in our clinical development program to move this therapy into broader populations, including platinum-sensitive disease. ELAHERE's differentiated safety and efficacy data provides further validation of our leading ADC platform and broad clinical pipeline of novel ADCs for solid tumors and hematologic malignancies."

In November 2022, the US Food and Drug Administration granted accelerated approval for ELAHERE for the treatment of adult patients with FRα-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens based on ORR and duration of response data from the pivotal SORAYA trial. Based on the MIRASOL results, ImmunoGen plans to submit an MAA to the European Medicines Agency and a sBLA to the FDA in the second half of this year.

CONFERENCE CALL INFORMATION
ImmunoGen will hold a conference call today at 8:00 AM. ET to discuss these results. To access the live call by phone, dial (877) 407-8835. 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 OVARIAN CANCER
Ovarian cancer is the leading cause of death from gynecological cancers in the US. Each year, roughly 20,000 patients are diagnosed, and 13,000 patients will die. Most patients present with late-stage disease and will typically undergo surgery followed by platinum-based chemotherapy. Unfortunately, the majority of patients eventually develop platinum-resistant disease, which is difficult to treat. In this setting, standard of care single-agent chemotherapies are associated with low response rates, short durations of response, and significant toxicities.

ABOUT ELAHERE
ELAHERE (mirvetuximab soravtansine-gynx) is a first-in-class ADC comprising a folate receptor alpha-binding antibody, cleavable linker, and the maytansinoid payload DM4, a potent tubulin inhibitor designed to kill the targeted cancer cells.

Indication and Usage
ELAHERE® is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Important Safety Information
BOXED WARNING: OCULAR TOXICITY

- ELAHERE can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.
- Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of ELAHERE, every other cycle for the first 8 cycles, and as clinically indicated.
- Administer prophylactic artificial tears and ophthalmic topical steroids.
- Withhold ELAHERE for ocular toxicities until improvement and resume at the same or reduced dose.
- Discontinue ELAHERE for Grade 4 ocular toxicities.

WARNINGS and PRECAUTIONS
Ocular Disorders
ELAHERE can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 61% of patients with ovarian cancer treated with ELAHERE. Nine percent (9%) of patients experienced Grade 3 ocular adverse reactions, including visual impairment, keratopathy/keratitis (corneal disorders), dry eye, photophobia, and eye pain; and one patient (0.2%) experienced Grade 4 keratopathy. The most common (≥5%) ocular adverse reactions were visual impairment (49%), keratopathy (36%), dry eye (26%), cataract (15%), photophobia (13%), and eye pain (12%).

The median time to onset for first ocular adverse reaction was 1.2 months (range: 0.03 to 12.9). Of the patients who experienced ocular events, 49% had complete resolution and 39% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade) at last follow up. Ocular adverse reactions led to permanent discontinuation of ELAHERE in 0.6% of patients.

Premedication and use of lubricating and ophthalmic topical steroids eye drops during treatment with ELAHERE are recommended. Advise patients to avoid use of contact lenses during treatment with ELAHERE unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue ELAHERE based on severity and persistence of ocular adverse reactions.

Pneumonitis
Severe, life-threatening, or fatal interstitial lung disease, including pneumonitis, can occur in patients treated with ELAHERE. Pneumonitis occurred in 10% of patients treated with ELAHERE, including 0.8% with Grade 3 events, and 1 patient (0.2%) with a Grade 4 event. One patient (0.2%) died due to respiratory failure in the setting of pneumonitis and lung metastases.

Monitor patients for pulmonary signs and symptoms of pneumonitis. Infectious, neoplastic, and other causes for symptoms should be excluded through appropriate investigations.

Withhold ELAHERE for patients who develop persistent or recurrent Grade 2 pneumonitis until symptoms resolve to ≤ Grade 1 and consider dose reduction. Permanently discontinue ELAHERE in all patients with Grade 3 or 4 pneumonitis. Patients who are asymptomatic may continue dosing of ELAHERE with close monitoring.

Peripheral Neuropathy (PN)
PN occurred in 36% of patients with ovarian cancer treated with ELAHERE across clinical trials; 2% of patients experienced Grade 3 PN. PN adverse reactions included peripheral neuropathy (19%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (2%), peripheral motor neuropathy (1%), neuralgia (0.4%), polyneuropathy (0.2%) and oral hypoesthesia (0.2%).

Monitor patients for signs and symptoms of neuropathy. For patients experiencing new or worsening PN, withhold dosage, dose reduce, or permanently discontinue ELAHERE based on the severity of PN.

Embryo-Fetal Toxicity
Based on its mechanism of action, ELAHERE can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ELAHERE and for 7 months after the last dose.

ADVERSE REACTIONS
Serious adverse reactions occurred in 31% of patients. The most common (≥2%) serious adverse reactions were intestinal obstruction (8%), ascites (4%), infection (3%), and pleural effusion (3%). Fatal adverse reactions occurred in 2% of patients, including small intestinal obstruction (1%) and pneumonitis (1%).

Permanent discontinuation of ELAHERE due to adverse reactions occurred in 11% of patients. The most common (≥2%) adverse reactions leading to permanent discontinuation were intestinal obstruction (2%) and thrombocytopenia (2%). One patient (0.9%) permanently discontinued ELAHERE due to visual impairment (unilateral decrease to BCVA < 20/200 that resolved to baseline after discontinuation).

Dosage delays of ELAHERE due to an adverse reaction occurred in 39% of patients. Adverse reactions which required dosage delays in ≥3% of patients included visual impairment (15%), keratopathy (11%), neutropenia (6%), dry eye (5%), cataracts (3%) and increased gamma-glutamyltransferase (3%).

Dose reductions of ELAHERE due to an adverse reaction occurred in 20% of patients. Adverse reactions which required dose reductions in ≥3% of patients included visual impairment (9%) and keratopathy (7%).

The most common (≥20%) adverse reactions, including laboratory abnormalities, were vision impairment, fatigue, increased aspartate aminotransferase, nausea, increased alanine aminotransferase, keratopathy, abdominal pain, decreased lymphocytes, peripheral neuropathy, diarrhea, decreased albumin, constipation, increased alkaline phosphatase, dry eye, decreased magnesium, decreased leukocytes, decreased neutrophils, and decreased hemoglobin.

DRUG INTERACTIONS
Strong CYP3A4 Inhibitors
DM4 is a CYP3A4 substrate. Concomitant use of ELAHERE with strong CYP3A4 inhibitors may increase unconjugated DM4 exposure, which may increase the risk of ELAHERE adverse reactions. Closely monitor patients for adverse reactions with ELAHERE when used concomitantly with strong CYP3A4 inhibitors.

USE IN SPECIAL POPULATIONS
Lactation
Advise women not to breastfeed during treatment with ELAHERE and for at least 1 month after the last dose.

Pediatric Use
Safety and effectiveness of ELAHERE have not been established in pediatric patients.

Hepatic Impairment
Avoid use of ELAHERE in patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN).

Please see full Prescribing Information, including Boxed Warning for ELAHERE.

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.

ELAHERE® is a trademark of ImmunoGen, Inc.

FORWARD-LOOKING STATEMENTS
This press release includes forward-looking statements. These statements include, but are not limited to, ImmunoGen's expectations related to the potential of ELAHERE to become the standard of care in FRa-positive ovarian cancer; the potential full approval of ELAHERE in the US and expansion to Europe, including the submission of a MAA in Europe and a sBLA in the US anticipated in the second half 2023; the presentation of full MIRASOL dater later this year; 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: top-line data may change as more patient data become available and are subject to audit and verification procedures;the timing and outcome of the Company's preclinical and clinical development processes; the results of the ongoing MIRASOL trial may not support full approval of ELAHERE and, if so, additional studies may be required; 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 anticipated interactions with regulatory authorities; the risk that the Company may not be able to obtain adequate price and reimbursement for any approved products, including the potential for delays or additional difficulties for ELAHERE in light of the FDA granting accelerated approval; 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 March 1, 2023, the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on April 28, 2023, 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. ImmunoGen 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.

INVESTOR RELATIONS CONTACT
ImmunoGen
Anabel Chan
781-895-0600
anabel.chan@immunogen.com

MEDIA CONTACTS
ImmunoGen
Courtney O'Konek
781-895-0600
courtney.okonek@immunogen.com

OR

FTI Consulting
Robert Stanislaro
212-850-5657
robert.stanislaro@fticonsulting.com