**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): July 31, 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 2.02 – RESULTS OF OPERATION AND FINANCIAL CONDITION**

On July 31, 2023, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the Company's financial results for the quarter and six months ended June 30, 2023. The press release announcing financial results for the quarter and six months ended June 30, 2023 is included as Exhibit 99.1 and incorporated herein by reference.

**ITEM 9.01 Financial Statements and Exhibits.**

(d): Exhibits

| Exhibit No. | Exhibit |
|---|---|
| 99.1 | Press Release of ImmunoGen, Inc. dated July 31, 2023 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL (eXtensible Business Reporting Language) 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.

**ImmunoGen, Inc.**
(Registrant)

Date: July 31, 2023

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

**Exhibit 99.1**

# ImmunoGen Reports Recent Progress and Second Quarter 2023 Financial Results

*Continued Strong Momentum with ELAHERE Launch in US; Net Sales of $77.4 Million in Q2*

*Presented Positive Results for ELAHERE from Phase 3 MIRASOL Trial During Late-Breaking Oral Presentation at ASCO; First Therapy to Demonstrate an Overall Survival Benefit Compared to Chemotherapy in a Phase 3 Trial in Platinum-Resistant Ovarian Cancer*

*Submission of ELAHERE MAA to Support Expansion into Europe and sBLA for Potential Full Approval in US on Track for Q4 2023*

*Presented Interim Analysis from Phase 2 CADENZA Trial at EHA Congress Showing Encouraging Anti-Tumor Activity and Durable Responses for Pivekimab Sunirine in BPDCN; Pivotal Frontline Cohort Now Fully Enrolled*

*Generated $350.8 Million in Net Proceeds from Public Equity Offering, Further Strengthening Balance Sheet*

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

Waltham, MA – July 31, 2023 – ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today reviewed recent progress in the business and reported financial results for the quarter ended June 30, 2023.

“This quarter we achieved a significant milestone for patients and our organization. With positive data from our confirmatory MIRASOL trial, ELAHERE is the first therapy to demonstrate an overall survival benefit versus chemotherapy in a Phase 3 trial in platinum-resistant ovarian cancer. These data further support the potential of ELAHERE to become the new standard of care for FRα-positive platinum-resistant disease,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “In parallel, through strong execution by our commercial team supported by robust engagement from medical affairs, we have accelerated the ELAHERE launch, more than doubling our Q1 results with increasing breadth and depth of adoption driven by recognition of the benefits this novel treatment brings to patients with advanced ovarian cancer.”

Enyedy continued, “We also progressed our broader development program to move ELAHERE into platinum-sensitive disease and position it as the combination agent of choice in ovarian cancer. Turning to our second pivotal program, PVEK, we presented an interim analysis from our CADENZA trial showing encouraging anti-tumor activity and durable responses in BPDCN and are pleased to share that we enrolled our last patient in the pivotal *de novo* frontline cohort at the end of the second quarter. We also advanced development with IMGC936 and IMGN151, our second-generation ADC targeting FRα. Looking ahead, we see continued momentum through the second half of the year with multiple data readouts and regulatory milestones, including efficacy results from PICCOLO with ELAHERE monotherapy in platinum-sensitive ovarian cancer and from the expansion cohorts with the PVEK/VEN/AZA triplet in frontline AML as well as the submissions of the MAA and sBLA for ELAHERE.”

**RECENT PROGRESS**

- Generated $77.4 million in ELAHERE® (mirvetuximab soravtansine-gynx) net sales for the quarter ended June 30, 2023.
- Announced positive data from the confirmatory Phase 3 MIRASOL trial in patients with folate receptor alpha (FRα)-positive platinum-resistant ovarian cancer (PROC) and presented the results in a late-breaking oral session at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting.
- Presented an interim analysis from the Phase 2 CADENZA trial of pivekimab sunirine (pivekimab) in patients with frontline and relapsed/refractory (R/R) blastic plasmacytoid dendritic cell neoplasm (BPDCN) at the European Hematology Association (EHA) 2023 Congress.
- Completed enrollment in the pivotal frontline *de novo* BPDCN cohort in the Phase 2 CADENZA trial.
- Our partner, Neopharm Israel, submitted the Marketing Authorization Application (MAA) to the Israeli Ministry of Health (MoH) for ELAHERE in FRα-positive PROC to support potential approval in mid-2024.

**ANTICIPATED UPCOMING EVENTS**

- Submit MAA to the European Medicines Agency (EMA) for ELAHERE in FRα-positive PROC in the fourth quarter of 2023 to support approval and launch in Europe.
- Submit supplemental Biologics License Application (sBLA) to the Food & Drug Administration (FDA) in the fourth quarter of 2023 to support the conversion of the accelerated approval of ELAHERE to full approval.
- Our partner, Huadong Medicine, expects to submit the MAA to the National Medical Products Administration (NMPA) of China for ELAHERE in FRα-positive PROC by the end of 2023 to support potential approval and launch.
- Present additional subset analyses from the Phase 3 MIRASOL trial in an oral session at the European Society of Gynaecological Oncology (ESGO) Congress in September.
- Report on the primary endpoint of objective response rate (ORR) for PICCOLO, a single-arm Phase 2 trial of mirvetuximab in FRα-high platinum-sensitive ovarian cancer (PSOC), before the end of 2023.
- Report data from two cohorts evaluating the pivekimab triplet with Venclexta® (venetoclax) and Vidaza® (azacitidine) in frontline acute myeloid leukemia (AML) at the American Society of Hematology (ASH) Annual Meeting in December.
- Provide an update on the IMGC936 non-small cell lung cancer (NSCLC) cohort following a prespecified interim analysis.

**FINANCIAL RESULTS**

Total revenues were $83.2 million for the quarter ended June 30, 2023, including $77.4 million of net product revenues from sales of ELAHERE, compared to $14.2 million in total revenues for the quarter ended June 30, 2022. The increase was primarily driven by ELAHERE net sales, partially offset by $6.9 million of license fees recorded as revenue in the prior year period pursuant to the Company's collaboration agreement with Huadong Medicine Co., Ltd (Huadong Medicine).

Research and development expenses were $50.1 million for the quarter ended June 30, 2023 compared to $51.4 million for the quarter ended June 30, 2022. The decrease was primarily driven by a $7.5 million one-time upfront fee recorded in the prior period related to our research collaboration with Oxford Biotherapeutics Ltd. and ELAHERE supply costs expensed in the prior quarter versus capitalized in the current period. Partially offsetting these decreases, third-party service fees and personnel costs increased driven largely by the expansion of our medical affairs organization, as well as an increase in clinical trial expenses in the current quarter.

Selling, general and administrative expenses were $36.4 million for the quarter ended June 30, 2023 compared to $23.8 million for the quarter ended June 30, 2022. The increase was due primarily to greater expenses in support of the US launch of ELAHERE, including costs related to the addition of our commercial organization and sales and marketing activities.

Net loss for the second quarter of 2023 was $4.2 million, or $0.02 per share, compared to a net loss of $62.0 million, or $0.24 per share, for the second quarter of 2022.

In May 2023, pursuant to a public equity offering, the Company sold an aggregate of 29,900,000 shares of its common stock, with net proceeds of $350.8 million.

ImmunoGen had $572.0 million in cash and cash equivalents and $75.4 million in accounts receivable as of June 30, 2023, compared with $275.1 million in cash and cash equivalents and $12.6 million in accounts receivable as of December 31, 2022. Cash used in operations was $140.5 million for the first six months of 2023 compared with cash used in operations of $105.4 million for the same period in 2022. Capital expenditures were $0.3 million and $0.5 million for the first six months of 2023 and 2022, respectively.

**FINANCIAL GUIDANCE**

ImmunoGen has updated its financial guidance for 2023 and now expects operating expenses of between $350 million and $365 million; this increase reflects greater spending in support of ELAHERE, including preparations for a launch in Europe, and to expand the Company's research capabilities and pipeline. Revenue guidance, excluding ELAHERE sales, remains unchanged at between $45 million and $50 million.

The Company expects that its existing cash and cash equivalents, together with anticipated future product and collaboration revenues, will fund operations for more than two years.

**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 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.

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.

Eye problems are common with ELAHERE and can be severe. ELAHERE also can cause severe or life-threatening inflammation of the lungs that may lead to death and patients may develop nerve problems called peripheral neuropathy during treatment. Please see full Prescribing Information, including Boxed Warning, and Medication Guide 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.

**FORWARD-LOOKING STATEMENTS**

*This press release includes forward-looking statements. These statements include, but are not limited to, the Company's expectations related to its revenues, operating expenses, and cash forecast; the potential of ELAHERE to become the standard of care and combination agent of choice in FRα-positive ovarian cancer; the potential full approval of ELAHERE in the US and regulatory approval of ELAHERE in Europe and China; the timing and presentation of clinical data on the Company's product candidates, including data from the MIRASOL trial, and data from the PICCOLO trial; the potential clinical benefits of pivekimab in BPDCN and AML and the potential for regulatory approval of pivekimab; 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; top-line data may change as more patient data become available and are subject to audit and verification procedures; 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 July 31, 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.*


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**SELECTED FINANCIAL INFORMATION**
**(in thousands, except per share amounts)**

**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(Unaudited)**

| | June 30, 2023 | December 31, 2022 |
|---|---|---|
| ASSETS | | |
| Cash and cash equivalents | $ 571,987 | $ 275,138 |
| Other assets | 142,340 | 73,798 |
| Total assets | $ 714,327 | $ 348,936 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current portion of deferred revenue | $ 14,389 | $ 13,856 |
| Other current liabilities | 79,313 | 108,002 |
| Term loan, net | 71,957 | - |
| Long-term portion of deferred revenue | 30,217 | 36,355 |
| Other long-term liabilities | 27,609 | 34,897 |
| Shareholders' equity | 490,842 | 155,826 |
| Total liabilities and shareholders' equity | $ 714,327 | $ 348,936 |

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
**(Unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| Revenues: | | | | |
| Product revenue, net | $ 77,371 | $ - | $ 106,915 | $ - |
| License and milestone fees | 40 | 6,973 | 15,071 | 37,865 |
| Non-cash royalty revenue | 5,742 | 7,116 | 10,581 | 13,544 |
| Research and development support | - | 73 | 455 | 831 |
| Total revenues | 83,153 | 14,162 | 133,022 | 52,240 |
| Cost and operating expenses: | | | | |
| Cost of sales | 909 | - | 1,535 | - |
| Research and development | 50,077 | 51,422 | 101,697 | 95,704 |
| Selling, general and administrative | 36,356 | 23,793 | 76,372 | 40,441 |
| Total cost and operating expenses | 87,342 | 75,215 | 179,604 | 136,145 |
| Interest income (expense), net | 1,905 | 590 | 4,074 | 644 |
| Non-cash interest expense on liability related to sale of future royalties and term loan | (1,079) | (1,078) | (1,932) | (2,327) |
| Other (loss) income, net | (8) | (480) | 55 | (578) |
| Loss before income taxes | $ (3,371) | $ (62,021) | $ (44,385) | $ (86,166) |
| Income tax expense | 877 | - | 877 | - |
| Net Loss | $ (4,248) | $ (62,021) | $ (45,262) | $ (86,166) |
| Basic and diluted net loss per common share | $ (0.02) | $ (0.24) | $ (0.17) | $ (0.34) |
| Basic and diluted weighted average common shares outstanding | 263,446 | 253,336 | 261,160 | 253,263 |