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): November 2, 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 November 2, 2023, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the Company's financial results for the quarter and nine months ended September 30, 2023. The press release announcing financial results for the quarter and nine months ended September 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 November 2, 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: November 2, 2023

/s/ Renee Lentini
Renee Lentini
Vice President - Finance, Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 99.1

ImmunoGen Reports Recent Progress and Third Quarter 2023 Financial Results

Continued Strong Demand for ELAHERE; US Net Sales of $105.2 Million in Q3

ELAHERE MAA in FRα-Positive Platinum-Resistant Ovarian Cancer Accepted by EMA; sBLA to Support Full Approval in US Submitted to FDA

PICCOLO Trial of ELAHERE in Platinum-Sensitive Ovarian Cancer Meets Primary Endpoint of Objective Response Rate; Full Data Anticipated in Mid-2024

Advanced Geographic Market Expansion Through Collaboration with Takeda to Develop and Commercialize ELAHERE in Japan and Acceptance of NDA by the NMPA in China

Expanded Leadership Team with Appointments of Lauren White, Chief Financial Officer, and Heather Adkins Huet, Chief Scientific Officer

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

Waltham, MA – November 2, 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 September 30, 2023.

“Building on the momentum generated in the first half of 2023, we delivered a strong third quarter highlighted by significant ELAHERE revenue growth and the achievement of key operational milestones,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “With a 36% increase in sequential quarterly net sales and over $210 million in product revenue through the first nine months of the year, ELAHERE is tracking towards one of the most successful first product launches in oncology in a decade. We also made important progress in our effort to bring ELAHERE to eligible patients around the world with the acceptance of the MAA by the EMA and the NDA by the NMPA, and the establishment of a collaboration with Takeda to deliver ELAHERE in Japan.”

Enyedy continued, “In addition, we advanced the ELAHERE development program and are pleased to report that our PICCOLO trial in platinum-sensitive ovarian cancer has met the primary endpoint of objective response rate based on an interim efficacy assessment. With a number of patients remaining on treatment and longer follow-up required to establish mature response durability of ELAHERE in this patient population, we anticipate an ORR of at least 48% when we report full data in mid-2024. Turning to our second pivotal program, PVEK, we continue to advance our 802 study and look forward to reporting data from our PVEK/VEN/AZA triplet in frontline AML at ASH in December. We also continued to monitor the NSCLC cohort with IMGC936 and advanced dose escalation with IMGN151, our second-generation ADC targeting FRα. We look forward to a strong finish to the year and a productive 2024 with the continued growth of ELAHERE, important new data for our programs, and geographic expansion in Europe and China.”

RECENT PROGRESS

ELAHERE (mirvetuximab soravtansine-gynx)

- Generated $105.2 million in ELAHERE net sales for the quarter ended September 30, 2023.
- Obtained acceptance of the Marketing Authorization Application (MAA) by the European Medicines Agency (EMA) for ELAHERE in folate receptor alpha (FRα)-positive platinum-resistant ovarian cancer (PROC) to support approval and launch in Europe.
- Submitted the supplemental Biologics License Application (sBLA) to the US Food and Drug Administration (FDA) to support conversion to full approval.

- Our partner, Huadong Medicine, obtained acceptance of the New Drug Application (NDA) to the National Medical Products Administration (NMPA) of China for ELAHERE in FRα-positive PROC to support approval and launch.
- Announced collaboration with Takeda Pharmaceutical Company Limited (Takeda) granting Takeda an exclusive license to develop and commercialize ELAHERE in Japan. The Company received an upfront payment of $23.2[1] million and is eligible to receive up to approximately $135[2] million in regulatory and commercial milestone payments in addition to tiered royalties in the low double-digits to mid-twenties.

Clinical Pipeline and Research

- Presented additional subset analyses in prior lines of therapy and prior exposure to PARP inhibitor (PARPi) therapy from MIRASOL in an oral session at the 24th Congress of the European Society of Gynaecological Oncology (ESGO) demonstrating clinical outcomes of safety and efficacy consistent with the overall MIRASOL study population.
- Reported that PICCOLO, the ongoing single-arm Phase 2 trial of mirvetuximab in FRα-high, platinum-sensitive ovarian cancer (PSOC) has met the primary endpoint of objective response rate (ORR) based upon an interim assessment with no new safety signals identified. An ORR of at least 48% is expected when full data are reported in mid-2024.
- Established a multi-target license and option agreement with ImmunoBiochem Corporation to develop next-generation ADCs.

Corporate

- Appointed Lauren White as Senior Vice President and Chief Financial Officer, and Heather Adkins Huet, PhD, as Senior Vice President and Chief Scientific Officer.

ANTICIPATED UPCOMING EVENTS

- Potential FDA approval of ELAHERE's sBLA in H1 2024.
- Report full data from the single-arm Phase 2 PICCOLO trial of mirvetuximab in FRα-high PSOC in mid-2024.
- Potential EMA approval of ELAHERE in late 2024 to support launch in Europe.
- Our partner, Huadong Medicine, is planning for NMPA approval of ELAHERE by the end of 2024 to support launch in China.
- Report data from the 802 trial, evaluating the pivekimab sunirine (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 2023.
- Report top-line data from the pivotal frontline *de novo* cohort in the Phase 2 CADENZA trial of pivekimab in blastic plasmacytoid dendritic cell neoplasm (BPDCN) in 2024.
- Provide an update on the IMGC936 non-small cell lung cancer (NSCLC) cohort following a prespecified interim analysis.

FINANCIAL RESULTS

Total revenues were $113.4 million for the quarter ended September 30, 2023, including $105.2 million of net product revenues from sales of ELAHERE, compared to $15.4 million in total revenues for the quarter ended September 30, 2022. The increase was driven by ELAHERE net sales, partially offset by $7.4 million of license fees recorded as revenue in the prior year period pursuant to the Company's collaboration agreements with Eli Lilly and Company and Novartis Institutes for BioMedical Research, Inc.

Research and development expenses were $47.6 million for the quarter ended September 30, 2023 compared to $59.2 million for the quarter ended September 30, 2022. The decrease was primarily driven by ELAHERE supply costs expensed in the prior quarter versus capitalized in the current period and lower hiring expenses. Partially offsetting these decreases, salaries and benefits increased driven largely by the expansion of our medical affairs organization.

Selling, general and administrative expenses were $37.7 million for the quarter ended September 30, 2023 compared to $33.6 million for the quarter ended September 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 income for the third quarter of 2023 was $30.7 million, or $0.10 per basic and diluted share, compared to a net loss of $77.8 million, or $0.31 per basic and diluted share, for the third quarter of 2022.

ImmunoGen had $605.5 million in cash and cash equivalents and $130.7 million in accounts receivable as of September 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 $137.7 million for the first nine months of 2023 compared with cash used in operations of $169.6 million for the same period in 2022. Capital expenditures were $1.6 million and $1.1 million for the first nine months of 2023 and 2022, respectively.

FINANCIAL GUIDANCE

ImmunoGen's full year financial guidance for 2023 remains unchanged; the Company continues to expect:

- revenues, excluding product revenue from ELAHERE, between $45 million and $50 million; and
- operating expenses between $350 million and $365 million.

The Company continues to expect 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.

[1] ¥3.4 billion (0.0068 exchange rate as of September 5, 2023); [2] ¥19.9 billion (0.0068 exchange rate as of August 25, 2023)

FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. These statements include, but are not limited to, the timing and outcome of the submissions of a Marketing Authorization Application in Europe, a supplemental Biologics License Application in the US, and a New Drug Application in China; the potential development and commercialization of ELAHERE in Japan; the timing and presentation of clinical data on the Company's products and product candidates, including data from the PICCOLO trial, the pivekimab triplet, top-line data from the Phase 2 CADENZA trial, and IMGC936; the Company's revenues and operating expenses for 2023; the Company's anticipated cash runway; and the Company's future product and collaboration revenues. 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 successful execution of the collaboration with Takeda and their development and commercialization efforts; the timing and outcome of the Company's clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense, and results of clinical trials and regulatory processes; the timing and outcome of 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; 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 Reports 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)

	September 30, 2023	December 31, 2022
ASSETS		
Cash and cash equivalents	$ 605,535	$ 275,138
Accounts receivable	130,694	12,596
Inventory	33,768	16,196
Other assets	52,104	45,006
Total assets	$ 822,101	$ 348,936
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current portion of deferred revenue	$ 37,186	$ 13,856
Other current liabilities	97,474	108,002
Term loan, net	72,113	-
Long-term portion of deferred revenue	26,718	36,355
Other long-term liabilities	27,014	34,897
Shareholders' equity	561,596	155,826
Total liabilities and shareholders' equity	$ 822,101	$ 348,936

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product revenue, net	$ 105,164	$ -	$ 212,079	$ -
License and milestone fees	51	7,382	15,122	45,247
Non-cash royalty revenue	7,355	7,993	17,936	21,537
Research and development support	855	-	1,310	831
Total revenues	113,425	15,375	246,447	67,615
Cost and operating expenses:				
Cost of sales	2,155	-	3,690	-
Research and development	47,570	59,181	149,267	154,885
Selling, general and administrative	37,744	33,623	114,116	74,064
Total cost and operating expenses	87,469	92,804	267,073	228,949
Interest income (expense), net	4,844	1,539	8,918	2,183
Non-cash interest expense on liability related to sale of future royalties and term loan	(1,054)	(867)	(2,986)	(3,194)
Other loss, net	(164)	(998)	(109)	(1,576)
Income (loss) before income taxes	$ 29,582	$ (77,755)	$ (14,803)	$ (163,921)
Income tax benefit	1,166	-	289	-
Net income (loss)	$ 30,748	$ (77,755)	$ (14,514)	$ (163,921)
Net income (loss) per common share - basic	$ 0.10	$ (0.31)	$ (0.05)	$ (0.65)
Net income (loss) per common share - diluted	$ 0.10	$ (0.31)	$ (0.05)	$ (0.65)
Weighted average common shares outstanding - basic	273,341	253,511	265,265	253,371
Weighted average common shares outstanding - diluted	287,590	253,511	265,265	253,371