

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): April 28, 2023

ImmunoGen, Inc.

(Exact name of registrant as specified in its charter)

Massachusetts
(State or other jurisdiction of
incorporation)

0-17999
(Commission File Number)

04-2726691
(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:

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
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 April 28, 2023, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the Company's financial results for the quarter ended March 31, 2023. The press release announcing financial results for the quarter ended March 31, 2023 is included as Exhibit 99.1 and incorporated herein by reference.

ITEM 9.01 Financial Statements and Exhibits.

(d): Exhibits

<u>Exhibit No.</u>	<u>Exhibit</u>
99.1	Press Release of ImmunoGen, Inc. dated April 28, 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: April 28, 2023

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

ImmunoGen Reports Recent Progress and First Quarter 2023 Financial Results

Strong Adoption of ELAHERE; Net Sales of \$29.5 Million in First Full Quarter of Launch

Top-Line Results from Confirmatory MIRASOL Trial Anticipated in Early May; Expected to Support Full Approval of ELAHERE in the US and Expansion into Europe

Announced Non-Dilutive Financing for Up to \$175 Million to Strengthen Balance Sheet and Support Company's Growth Trajectory

Expanded Leadership Team with the Appointment of Isabel Kalofonos as Senior Vice President and Chief Commercial Officer

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

Waltham, MA - April 28, 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 March 31, 2023.

“With a strong first full quarter of sales and continued momentum in FR α testing and market access, we have started the year making great strides towards establishing ELAHERE as the standard of care for FR α -positive ovarian cancer,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “Our commercial and medical teams have delivered exemplary performances in the first stages of the ELAHERE launch and we look forward to continued success with the appointment of Isabel Kalofonos as our new Chief Commercial Officer.”

Enyedy continued, “With our goal of obtaining full approval for ELAHERE in the US and expanding into Europe, we expect to announce top-line data from our confirmatory MIRASOL trial in early May. In parallel, we advanced our broader development program to move into platinum-sensitive disease and position ELAHERE as the combination agent of choice in ovarian cancer. Turning to our second pivotal program, PVEK, we expect to complete enrollment in our pivotal CADENZA trial in frontline BPDCN by the end of the year. In addition, we anticipate reporting data from our expansion cohorts with the PVEK/VEN/AZA triplet in frontline AML at ASH in December. We also advanced dose escalation with IMG151, our second-generation ADC targeting FR α , and expect to report data for IMG936 following an interim analysis. With meaningful clinical milestones coming, strong commercial uptake of ELAHERE, and a strengthened balance sheet following our recent non-dilutive term loan financing with Pharmakon, we are well positioned to create significant value for both patients and shareholders throughout the year.”

RECENT PROGRESS

- Generated \$29.5 million in ELAHERE® (mirvetuximab soravtansine-gynx) net sales for the quarter ended March 31, 2023, the first full quarter of launch following approval in November of 2022.
 - Reached requisite number of progression-free survival (PFS) events in the confirmatory MIRASOL trial.
 - Presented final overall survival and additional efficacy data from the SORAYA trial at the Society of Gynecologic Oncology (SGO) 2023 Annual Meeting.
 - Advanced dose escalation with IMG151 and enrollment in the non-small cell lung cancer (NSCLC) expansion cohort for IMG936.
 - Announced non-dilutive credit facility with Pharmakon Advisors, LP for up to \$175 million; \$75 million received upon execution.
 - Appointed Isabel Kalofonos as Senior Vice President and Chief Commercial Officer.
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ANTICIPATED UPCOMING EVENTS

- Report top-line data for MIRASOL trial in early May 2023.
- Submit Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for ELAHERE in FR α -high platinum-resistant ovarian cancer (PROC) in the second half of 2023 to support approval and launch in Europe.
- Submit supplemental Biologics License Application (sBLA) to the FDA in the second half of 2023 to support the conversion of the accelerated approval of ELAHERE to full approval.
- Our partner, Huadong Medicine, to submit Biologics License Application (BLA) to the National Medical Products Administration (NMPA) of China for ELAHERE in FR α -high PROC in the second half of 2023 to support potential approval and launch.
- Report on primary endpoint for PICCOLO, a single-arm Phase 2 trial of mirvetuximab in FR α -high platinum-sensitive ovarian cancer (PSOC), before the end of 2023.
- Complete enrollment in the pivotal Phase 2 CADENZA trial this year.
- Initiate combination cohort of pivekimab with magrolimab in relapsed/refractory (R/R) acute myeloid leukemia (AML) in collaboration with Gilead in the second half of 2023.
- Report data from two cohorts evaluating the pivekimab triplet with Venclexta[®] (venetoclax) and Vidaza[®] (azacitidine) in frontline AML at the American Society of Hematology (ASH) Annual Meeting in December.
- Report data from the IMGC936 NSCLC cohort following an interim analysis.

FINANCIAL RESULTS

Total revenues were \$49.9 million for the quarter ended March 31, 2023, including \$29.5 million of net product revenues from sales of ELAHERE for the first full quarter of launch following approval in November 2022, compared to \$38.1 million in total revenue for the quarter ended March 31, 2022. The increase was primarily driven by ELAHERE net sales and recognition of a \$15 million upfront fee received pursuant to a multi-target license and option agreement executed in the first quarter with Vertex Pharmaceuticals, partially offset by \$30.8 million of license fees recorded as revenue in the prior year period pursuant to the Company's collaboration and license agreements with Huadong Medicine and Eli Lilly.

Research and development expenses rose to \$51.6 million for the quarter ended March 31, 2023 compared to \$44.3 million for the quarter ended March 31, 2022. The increase was primarily driven by costs related to the addition of our medical affairs organization and clinical trial expenses.

Selling, general and administrative expenses were \$40.0 million for the quarter ended March 31, 2023 compared to \$16.6 million for the quarter ended March 31, 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 first quarter of 2023 was \$41.0 million, or \$0.16 per diluted share, compared to net loss of \$24.1 million, or \$0.10 per diluted share, for the first quarter of 2022.

ImmunoGen had \$201.2 million in cash and cash equivalents as of March 31, 2023, compared with \$275.1 million as of December 31, 2022. Cash used in operations was \$73.7 million for the first three months of 2023 compared with cash used in operations of \$41.4 million for the same period in 2022. Capital expenditures were \$0.2 million and \$0.3 for the first three months of 2023 and 2022, respectively. Earlier this month, the Company entered into a term loan credit facility for up to \$175 million with entities managed by Pharmakon and drew the initial tranche of \$75 million upon execution of the facility.

FINANCIAL GUIDANCE

ImmunoGen has updated its financial guidance for 2023 and now expects:

- revenues, excluding product revenue from ELAHERE, between \$45 million and \$50 million; and
- operating expenses between \$320 million and \$335 million.

ImmunoGen expects to provide ELAHERE product revenue guidance later this year. The increase in revenue guidance is a result of recognizing a \$15 million upfront fee from Vertex in the first quarter as no deferral was required. Additionally, the Company increased its operating expense guidance to reflect greater spend in support of ELAHERE's launch and expected growth trajectory.



ImmunoGen expects that its current cash, inclusive of the \$75 million received pursuant to the term loan facility with Pharmakon, and combined with anticipated product and collaboration revenues, will fund operations into 2025.

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 (FR α) 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.

Vidaza[®] and Venclextra[®] are registered trademarks of their respective owners. ELAHERE[®] is a registered 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 Company's revenues, operating expenses, and cash position for 2023; the Company's anticipated cash runway; the potential of ELAHERE to become the standard of care and combination agent of choice in FR α -positive ovarian cancer, and the potential full approval of ELAHERE in the US and expansion to Europe; the timing and presentation of clinical data on the Company's product candidates, including data from the MIRASOL trial, data from the CADENZA trial, and data from the PICCOLO trial; 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 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 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)

	March 31, 2023	December 31, 2022
ASSETS		
Cash and cash equivalents	\$ 201,249	\$ 275,138
Other assets	87,096	73,798
Total assets	\$ 288,345	\$ 348,936
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current portion of deferred revenue	\$ 13,444	\$ 13,856
Other current liabilities	88,185	108,002
Long-term portion of deferred revenue	34,055	36,355
Other long-term liabilities	30,743	34,897
Shareholders' equity	121,918	155,826
Total liabilities and shareholders' equity	\$ 288,345	\$ 348,936



CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March	
	2023	2022
Revenues:		
Product revenue, net	\$ 29,544	\$ -
License and milestone fees	15,031	30,892
Non-cash royalty revenue	4,839	6,428
Research and development support	455	758
Total revenues	49,869	38,078
Cost and operating expenses:		
Cost of sales	626	-
Research and development	51,620	44,282
Selling, general and administrative	40,016	16,648
Total cost and operating expenses	92,262	60,930
Loss from operations	(42,393)	(22,852)
Non-cash interest expense on liability related to sale of future royalties	(853)	(1,249)
Other income (loss), net	2,232	(44)
Net Loss	\$ (41,014)	\$ (24,145)
Basic and diluted net loss per common share	\$ (0.16)	\$ (0.10)
Basic and diluted weighted average common shares outstanding	258,848	253,263