

IMMUNOGEN INC

FORM 8-K (Current report filing)

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Address	830 WINTER ST WALTHAM, MA, 02451
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**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 3, 2017**

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))

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 3, 2017, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the company's financial results for the quarter ended September 30, 2017. The press release announcing financial results for the quarter ended September 30, 2017 is included as Exhibit 99.1 and incorporated herein by reference.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(d): The following exhibit is being furnished herewith:

<u>Exhibit No.</u>	<u>Exhibit</u>
99.1	Press Release of ImmunoGen, Inc. dated November 3, 2017

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 3, 2017

/s/ David B. Johnston

David B. Johnston
Executive Vice President and Chief Financial Officer

IMMUNOGEN

ImmunoGen Reports Recent Progress and Third Quarter 2017 Operating Results

Collaboration with Jazz Pharmaceuticals Accelerates Development of Early-Stage ADC Assets and Strengthens Financial Position

\$100+ Million Follow-on Financing Provides Two-year Operating Runway

Presentations Accepted for ASH Annual Meeting Highlight Potential of Novel IGN Portfolio

IMGN632 Investigational New Drug Application Active

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

WALTHAM, Mass., Nov. 3, 2017 — ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today reviewed recent highlights and reported financial results for the quarter ended September 30, 2017.

“During the third quarter, we built upon the momentum in the business with strong operational execution and by significantly strengthening our capital position,” said Mark Enyedy, ImmunoGen’s president and chief executive officer. “The Jazz collaboration accelerates the development of our early-stage programs in hematological malignancies, and the proceeds from this transaction and the October financing extend our operating runway well beyond the expected timeframe of the readout of FORWARD I, our Phase 3 registration study for mirvetuximab. We are continuing to advance FORWARD I along with our FORWARD II trial evaluating mirvetuximab in multiple combination regimens, and look forward to presenting data on IMGN779 and IMGN632 at the ASH Annual Meeting in December and opening the Phase 1 study for IMGN632 by year-end. Based on the progress made this year, we will enter 2018 with FORWARD I on track to complete enrollment by mid-year, clinical proof-of-concept for mirvetuximab’s potential role as a combination therapy, two agents deploying our novel IGN payload in the clinic, and a strong balance sheet.”

Recent Highlights

Proprietary Portfolio

- Investigational new drug (IND) application activated to support clinical testing with IMGN632, a CD123-targeting ADC integrating a potent DNA-alkylating payload intended to treat a range of hematological malignancies, including acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN);
 - Abstracts highlighting clinical and preclinical data for IMGN779, including updated safety and anti-leukemia activity from the dose-escalation phase of the IMGN779 first-in-human trial, and preclinical data for IMGN632 accepted for presentation at the 2017 American Society of Hematology (ASH) Annual Meeting; and
 - FORWARD I and FORWARD II trials advancing in North America and Europe.
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Business Development

- Strategic collaboration and option agreement with Jazz Pharmaceuticals established, covering the development and commercialization of IMGN779 and IMGN632, as well as an additional program to be named during the term of the collaboration. ImmunoGen received a \$75 million upfront fee in the third quarter under this agreement.

Balance Sheet

- Completed an underwritten public offering of 16,675,000 shares of common stock raising net proceeds of \$101.6 million (after deducting the underwriting discounts and offering expenses) in October; and
- Converted \$96.9 million of debt outstanding into 25,882,421 shares of the Company's common stock, reducing the aggregate principal amount of the Company's convertible debt to \$3.1 million.

Partner Programs

- Bayer announced findings at the World Conference on Lung Cancer from the pivotal Phase 2 trial assessing anetumab ravtansine, an ADC in development for patients with recurrent malignant pleural mesothelioma. Bayer is evaluating anetumab ravtansine in a variety of solid tumor indications, including as combination therapy and also presented data from a Phase 1b study assessing anetumab ravtansine in combination with pemetrexed and cisplatin in mesothelin-expressing predominantly epithelial mesothelioma or nonsquamous non-small cell lung cancer at the AACR-NCI-EORTC meeting; and
- Takeda presented preclinical data at the AACR-NCI-EORTC meeting with TAK-164, an ADC directed to GCC-positive solid tumors using ImmunoGen's IGN platform.

Anticipated Upcoming Events

- Report updated Phase 1 clinical data for IMGN779 in adult patients with relapsed or refractory AML, IMGN779 preclinical combination data, and IMGN632 preclinical data at ASH annual meeting;
- Open a Phase 1 study for IMGN632 before year-end;
- Activate more than 100 sites globally for the FORWARD I trial by year-end;
- Initiate a cohort in the FORWARD II study to evaluate the triplet combination of mirvetuximab soravtansine/Avastin[®] (bevacizumab)/carboplatin in patients with platinum sensitive folate receptor alpha (FR α)-positive epithelial ovarian cancer in 1Q 2018; and
- Report updated dose escalation findings from the Phase 1b/2 FORWARD II Keytruda[®] (pembrolizumab) cohort, along with updated data from the Avastin[®] expansion cohort in the first half of 2018.

Financial Results

Revenues for the quarter ended September 30, 2017 were \$8.5 million, compared to \$7.7 million for the quarter ended September 30, 2016. Revenues in the third quarter of 2017 included \$6.5

million in non-cash royalty revenues, compared with \$6.2 million in non-cash royalty revenues for the same quarter in 2016. Revenues for the third quarter of 2017 also included \$0.7 million of research and development (R&D) support fees and \$1.2 million of clinical materials revenue, compared with \$1.4 million and \$0.1 million, respectively, for the same quarter in 2016.

Operating expenses for the third quarter of 2017 were \$39.6 million, compared to \$46.5 million for the same quarter in 2016. Operating expenses in the third quarter of 2017 include R&D expenses of \$31.7 million, compared to \$32.9 million for the same quarter in 2016. This change is primarily due to a workforce reduction resulting from the strategic review in September 2016 and lower third party costs, partially offset by increased clinical trial costs driven primarily by the advancement of the FORWARD I Phase 3 clinical trial. Operating expenses include general and administrative expenses of \$7.9 million in the third quarter of 2017 compared to \$9.5 million in the same quarter in 2016. This decrease is primarily due to lower personnel expenses and third-party service fees. Operating expenses in the prior period also include a \$4.1 million restructuring charge related to the workforce reduction and a loss on leased office space.

During the third quarter of 2017, \$96.9 million of convertible debt outstanding was converted into 25,882,421 shares of the Company's common stock, resulting in a \$22.2 million non-cash debt conversion charge recorded in the current period. With this conversion, the Company's outstanding debt is reduced to \$3.1 million.

ImmunoGen reported a net loss of \$56.7 million, or \$0.61 per basic and diluted share, for the third quarter of 2017 compared to a net loss of \$44.7 million, or \$0.51 per basic and diluted share, for the same quarter last year. This increase is primarily due to the \$22.2 million non-cash charge relating to the conversion of the debt.

ImmunoGen had \$194.9 million in cash and cash equivalents as of September 30, 2017, compared with \$160.0 million as of December 31, 2016, and had \$3.1 million and \$100.0 million of convertible debt outstanding as of September 30, 2017 and December 31, 2016, respectively. Cash provided by operations was \$37.1 million for the first nine months of 2017, compared with cash used in operations of \$(106.8) million for the same period in 2016. The current period benefited from a \$30 million paid-up license fee received from Sanofi, which is included in revenue in the current period, a \$75 million upfront payment received from Jazz and a \$25 million upfront payment received from Debiopharm, both of which are included in deferred revenue as of September 30, 2017. Capital expenditures were \$0.8 million and \$6.4 million for the nine months ended September 30, 2017 and 2016, respectively.

In October 2017, pursuant to a public offering, the Company sold an aggregate of 16,675,000 shares of its common stock, with net proceeds to the Company of \$101.6 million, after deducting underwriting discounts and estimated offering expenses.

Financial Guidance

ImmunoGen has updated its guidance for 2017. Cash and cash equivalents at December 31, 2017 are expected to be between \$260 million and \$265 million, compared to previous guidance of

\$90 million to \$95 million. These changes are a result of the Jazz agreement executed in the third quarter of 2017 and the proceeds provided by the public stock offering in October 2017. Revenue guidance remains unchanged and is expected to be between \$115 million and \$120 million.

Operating expenses are now expected to be between \$170 and \$175 million, compared to previous guidance of \$175 to \$180 million.

ImmunoGen expects that its current cash combined with the expected cash revenues from partners and collaborators will enable the Company to fund its operations into the fourth quarter of 2019.

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 719-325-4907; the conference ID is 6498153. The call may also be accessed through the Investors section of the Company's website, www.immunogen.com. Following the live webcast, a replay of the call will be available at the same location through November 17, 2017.

About ImmunoGen, Inc.

ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using its proprietary ADC technology. The Company's lead product candidate, mirvetuximab soravtansine, is in a Phase 3 trial for FR α -positive platinum-resistant ovarian cancer, and is in a Phase 1b/2 trial in combination regimens for earlier-stage disease. ImmunoGen has three additional clinical-stage product candidates, two of which are being developed in collaboration with Jazz Pharmaceuticals. ImmunoGen's ADC technology is also used in Roche's marketed product, Kadcyla[®], and in programs in development by Amgen, Bayer, Biotest, CytomX, Debiopharm, Lilly, Novartis, Sanofi and Takeda. More information about the Company can be found at www.immunogen.com.

Kadcyla[®] is a registered trademark of Genentech, a member of the Roche Group.

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This press release includes forward-looking statements based on management's current expectations. These statements include, but are not limited to, ImmunoGen's expectations related to: the Company's revenues, operating expenses, net loss, cash used in operations and capital expenditures for the twelve months ending December 31, 2017; its cash and marketable securities as of December 31, 2017; the occurrence, timing and outcome of potential pre-clinical, clinical and regulatory events related to the Company's and its collaboration partners' product programs; and the presentation of preclinical and clinical data on the Company's and collaboration partners' product candidates. For these statements, ImmunoGen claims the protection of the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. 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 ImmunoGen's and the Company's collaboration partners' research 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; ImmunoGen's ability to financially support its product programs; ImmunoGen's dependence on collaborative partners; industry merger and acquisition activity; and other factors more fully described in ImmunoGen's Transition Report on Form 10-KT for the six-month period ended December 31, 2016 and other reports filed with the Securities and Exchange Commission.

-Financials Follow-

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

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2017	December 31, 2016
ASSETS		
Cash and cash equivalents	\$ 194,851	\$ 159,964
Other assets	30,844	38,900
Total assets	\$ 225,695	\$ 198,864
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current portion of deferred revenue	\$ 27,073	\$ 14,531
Other current liabilities	46,582	41,245
Long-term portion of deferred revenue	93,832	19,086
Other long-term liabilities	169,503	276,852
Shareholders' deficit	(111,295)	(152,850)
Total liabilities and shareholders' deficit	\$ 225,695	\$ 198,864

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
License and milestone fees	\$ 79	\$ 76	\$ 49,889	\$ 10,229
Non-cash royalty revenue	6,503	6,184	20,555	19,508
Research and development support	650	1,354	3,030	3,748
Clinical materials revenue	1,248	46	2,525	1,297
Total revenues	8,480	7,660	75,999	34,782
Expenses:				
Research and development	31,689	32,909	99,896	107,655
General and administrative	7,908	9,459	24,863	29,992
Restructuring charge	—	4,130	386	4,130
Total operating expenses	39,597	46,498	125,145	141,777
Loss from operations	(31,117)	(38,838)	(49,146)	(106,995)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(3,385)	(5,018)	(10,461)	(14,946)
Non-cash debt conversion expense	(22,191)	—	(22,191)	—
Interest expense on convertible bonds	(762)	(1,150)	(3,012)	(1,288)
Other income, net	773	275	1,916	648
Net loss	\$ (56,682)	\$ (44,731)	\$ (82,894)	\$ (122,581)
Net loss per common share, basic and diluted	\$ (0.61)	\$ (0.51)	\$ (0.93)	\$ (1.41)
Weighted average common shares outstanding, basic and diluted	93,001	87,102	89,133	87,029