

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): **July 28, 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 July 28, 2017, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the company's financial results for the quarter ended June 30, 2017. The press release announcing financial results for the quarter ended June 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 June 30, 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: July 28, 2017

/s/ David B. Johnston

David B. Johnston
Executive Vice President and Chief Financial Officer

IMMUNOGEN

ImmunoGen Reports Recent Progress and Second Quarter 2017 Operating Results

Data Presented at ASCO Support Broad Potential of Mirvetuximab Soravtansine in Ovarian Cancer

Sanofi and Debiopharm Transactions Strengthen Cash Position

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

WALTHAM, Mass., July 28, 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 June 30, 2017.

“We made substantial progress during the second quarter towards our strategic priorities, generating compelling data with our lead program, advancing our novel pipeline, and strengthening our balance sheet,” said Mark Enyedy, ImmunoGen’s president and chief executive officer. “We reported single-agent and combination therapy data with mirvetuximab soravtansine in over 150 patients at ASCO, which strengthen our confidence in the potential of mirvetuximab in the FORWARD I patient population and as we move into earlier lines of treatment for ovarian cancer. In addition, we presented encouraging initial clinical results for IMGN779 in AML, demonstrating dose-dependent biological and anti-leukemia activity, and the ability to retreat patients. Lastly, we significantly improved our cash position through transactions with Sanofi and Debiopharm, enabling us to increase our focus on the development of mirvetuximab and our IGN programs. We look forward to continued execution on these programs over the back half of the year, including filing the IND for IMGN632, our novel CD123-targeting ADC for hematological malignancies.”

Recent Highlights

Proprietary Portfolio

- Presented pooled analyses of three Phase 1 expansion cohorts at the American Society of Clinical Oncology (ASCO) Annual Meeting, demonstrating the safety and efficacy profile of mirvetuximab soravtansine in the patient population being enrolled in FORWARD I, the ongoing Phase 3 registration trial in women with folate receptor alpha (FR α)-positive ovarian cancer;
 - Presented encouraging data from the Phase 1b/2 FORWARD II study at ASCO, evaluating mirvetuximab soravtansine in combination with Avastin® (bevacizumab), carboplatin, Doxil® (pegylated liposomal doxorubicin), or Keytruda® (pembrolizumab), demonstrating its potential to complement currently available therapies for FR α -positive ovarian cancer in a range of treatment settings, including earlier lines of therapy; and
 - Presented first-in-human data at the 22nd Congress of the European Hematology Association (EHA) on IMGN779 in patients with relapsed or refractory adult acute myeloid leukemia (AML), whose tumors express CD33, demonstrating safety and tolerability across seven dose levels, with no dose limiting toxicities, as well as evidence of dose-dependent biological and anti-leukemia activity.
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Partner Programs

- In exchange for a \$30 million payment, ImmunoGen granted sanofi-aventis U.S. LLC (Sanofi) a fully-paid, exclusive license to develop, manufacture, and commercialize the following experimental agents in development: isatuximab (SAR650984), an unconjugated anti-CD38 antibody in Phase 3 development for relapsed and refractory multiple myeloma; SAR566658, an ADC targeting CA6; SAR408701, an anti-CEACAM5 ADC; an additional ADC directed to an undisclosed target; and SAR428926, an ADC targeting LAMP1;
- In exchange for a \$25 million upfront payment, Debiopharm International, S.A. (Debiopharm) acquired the Company's IMGN529/DEBIO 1562, a clinical-stage anti-CD37 ADC for the treatment of patients with B-cell malignancies, such as non-Hodgkin lymphoma. ImmunoGen will receive a \$5 million milestone payment upon completion of the transfer of technologies related to the asset, which is expected before year end, and is also eligible for a second success-based milestone payment of \$25 million upon IMGN529/DEBIO 1562 entering a Phase 3 clinical trial;
- CytomX announced the treatment of the first patient in a Phase 1/2 clinical trial evaluating CX-2009, a Probody™ drug conjugate, as monotherapy in select advanced solid tumors, resulting in a \$1 million milestone payment to ImmunoGen; and
- Bayer announced that the Phase 2 trial assessing anetumab ravtansine in patients with recurrent malignant pleural mesothelioma did not meet its primary endpoint of progression-free survival. The safety and tolerability of anetumab ravtansine were consistent with earlier clinical findings and Bayer is continuing development in additional studies, including a Phase 1b multi-indication study in six different types of advanced solid tumors, and a Phase 1b combination-study in patients with recurrent platinum-resistant ovarian cancer.

Additional Upcoming Events

- ImmunoGen anticipates filing an investigational new drug (IND) application in the third quarter of 2017 to support clinical testing with IMGN632, a CD123-targeting ADC integrating a more potent DNA-alkylating payload intended to treat a range of hematological malignancies.
- The Company expects to present updated clinical data for IMGN779 in patients with relapsed or refractory adult AML at an upcoming medical meeting.
- ImmunoGen plans to publish results from the 40 patient Phase 1 mirvetuximab soravtansine expansion cohort evaluating the use of prophylactic steroid eye drops. The findings support the use of eye drops in the Phase 3 FORWARD I trial.

Financial Results

Revenues for the quarter ended June 30, 2017 were \$39.0 million, compared to \$7.4 million for the quarter ended June 30, 2016. License and milestone fees for the second quarter of 2017 included a \$30 million paid-up license fee related to an amendment to the Company's collaboration and license agreement with Sanofi and a \$1 million Phase 1 milestone payment

pursuant to the Company's license agreement with CytomX. Revenues in the second quarter of 2017 included \$6.4 million in non-cash royalty revenues, compared with \$5.9 million in non-cash royalty revenues for the same quarter in 2016. Revenues for the second quarter of 2017 also included \$0.9 million of research and development (R&D) support fees and \$0.6 million of clinical materials revenue, compared with \$1.3 million and \$0.1 million, respectively, for the same quarter in 2016.

Operating expenses for the second quarter of 2017 were \$44.2 million, compared to \$48.0 million for the same quarter in 2016. Operating expenses in the second quarter of 2017 include R&D expenses of \$35.3 million, compared to \$38.7 million for the same quarter in 2016. This change is primarily due to a workforce reduction resulting from the strategic review in September 2016, decreased clinical trial costs driven by the Phase 1 mirvetuximab soravtansine and IMG529 studies winding down, and lower third party costs. These decreases were partially offset by increased costs related to the FORWARD I Phase 3 clinical trial, as well as an increase in antibody expense driven by mirvetuximab soravtansine commercial-readiness activities. Operating expenses include general and administrative expenses of \$8.8 million in the second quarter of 2017 compared to \$9.3 million in the same quarter in 2016. This decrease is primarily due to decreased personnel expenses.

ImmunoGen reported a net loss of \$8.9 million, or \$0.10 per basic and diluted share, for the second quarter of 2017 compared to a net loss of \$45.9 million, or \$0.53 per basic and diluted share, for the same quarter last year.

ImmunoGen had approximately \$150.3 million in cash and cash equivalents as of June 30, 2017, compared with \$160.0 million as of December 31, 2016, and had \$100.0 million of convertible debt outstanding in each period. Cash used in operations was \$8.9 million for the first six months of 2017, compared with \$59.0 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, and a \$25 million upfront payment received from Debiopharm that is included in deferred revenue as of June 30, 2017. Capital expenditures were \$0.8 million and \$5.2 million for the six months ended June 30, 2017 and 2016, respectively.

Financial Guidance

ImmunoGen has updated its guidance for 2017. Expected revenues are now projected to be between \$115 million and \$120 million, compared with previous guidance of between \$70 million and \$75 million; and cash and cash equivalents at December 31, 2017 are expected to be between \$90 million and \$95 million, compared to previous guidance of \$35 million to \$40 million. These changes are a result of the Debiopharm and Sanofi agreements executed in the second quarter of 2017. Operating expenses remain unchanged and are expected to be between \$175 million and \$180 million.

ImmunoGen expects that its current cash plus expected cash revenues from partners and collaborators will enable the Company to fund operations into the second half of 2018.

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 719-325-4845; the conference ID is 8195001. 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 August 11, 2017.

About ImmunoGen, Inc.

ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using its proprietary antibody-drug conjugate (ADC) technology. ImmunoGen's lead product candidate, mirvetuximab soravtansine, is in a Phase 3 trial for FR α -positive platinum-resistant ovarian cancer, and is in Phase 1b/2 testing in combination regimens for earlier-stage disease. ImmunoGen's ADC technology is used in Roche's marketed product, Kadcyla[®], in other clinical-stage ImmunoGen product candidates, 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 Annual Report on Form 10-K 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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IMMUNOGEN, INC.
SELECTED FINANCIAL INFORMATION
(in thousands, except per share amounts)

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	<u>June 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
ASSETS		
Cash and cash equivalents	\$ 150,337	\$ 159,964
Other assets	31,040	38,900
Total assets	<u>\$ 181,377</u>	<u>\$ 198,864</u>
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities	\$ 67,350	\$ 55,776
Long-term portion of deferred revenue and other long-term liabilities	287,256	295,938
Shareholders' deficit	<u>(173,229)</u>	<u>(152,850)</u>
Total liabilities and shareholders' deficit	<u>\$ 181,377</u>	<u>\$ 198,864</u>

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	<u>Three Months Ended</u> <u>June 30,</u>		<u>Six Months Ended</u> <u>June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Revenues:				
License and milestone fees	\$ 31,080	\$ 76	\$ 49,810	\$ 10,153
Non-cash royalty revenue	6,439	5,944	14,052	13,324
Research and development support	902	1,335	2,380	2,394
Clinical materials revenue	599	53	1,277	1,251
Total revenues	<u>39,020</u>	<u>7,408</u>	<u>67,519</u>	<u>27,122</u>
Expenses:				
Research and development	35,319	38,652	68,207	74,746
General and administrative	8,836	9,298	16,955	20,533
Restructuring charge	—	—	386	—
Total operating expenses	<u>44,155</u>	<u>47,950</u>	<u>85,548</u>	<u>95,279</u>
Loss from operations	(5,135)	(40,542)	(18,029)	(68,157)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(3,501)	(4,956)	(7,076)	(9,928)
Interest expense on convertible bonds	(1,125)	(138)	(2,250)	(138)
Other income (loss), net	894	(286)	1,143	373
Net loss	<u>\$ (8,867)</u>	<u>\$ (45,922)</u>	<u>\$ (26,212)</u>	<u>\$ (77,850)</u>
Net loss per common share, basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.53)</u>	<u>\$ (0.30)</u>	<u>\$ (0.89)</u>
Weighted average common shares outstanding, diluted	<u>87,174</u>	<u>87,062</u>	<u>87,167</u>	<u>87,029</u>