

IMMUNOGEN INC

FORM 8-K (Current report filing)

Filed 05/05/17 for the Period Ending 05/05/17

Address	830 WINTER ST WALTHAM, MA 02451
Telephone	(781)895-0600
CIK	0000855654
Symbol	IMGN
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	06/30

**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): **May 5, 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 May 5, 2017, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the company's financial results for the quarter ended March 31, 2017. The press release announcing financial results for the quarter ended March 31, 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 May 5, 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: May 5, 2017

/s/ David B. Johnston

David B. Johnston
Executive Vice President and Chief Financial Officer

IMMUNOGEN

ImmunoGen Reports Recent Progress and First Quarter 2017 Operating Results

*Phase 3 FORWARD I Trial of Mirvetuximab Soravtansine Activated in North America and Europe
Data at AACR and SGO Annual Meetings Highlight Patient Selection Strategy for FORWARD I and Breadth of ADC Expertise
Mirvetuximab Soravtansine Safety and Efficacy Data to be Presented at ASCO Annual Meeting
Conference Call to be Held at 8:00am ET Today*

WALTHAM, Mass., May 5, 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 March 31, 2017.

“We have started 2017 with significant progress towards our strategic priorities of advancing our portfolio, supporting our partners, and driving continued innovation in ADCs,” said Mark Enyedy, ImmunoGen’s president and chief executive officer. “Following enrollment of our first patient in FORWARD I in January, we have since expanded the study to include additional centers in North America and Europe, and expect to activate more than 100 sites in these geographies before the end of the year. We presented data at the SGO Annual Meeting supporting our patient selection strategy for FORWARD I and delivered nine presentations at the AACR Annual Meeting highlighting novel ADCs and enhancements to our platform technologies. For the remainder of the year, we look forward to a number of additional milestones, including sharing new efficacy and safety data for mirvetuximab soravtansine at ASCO and filing an IND for our CD123-targeting ADC, IMGN632, in the third quarter.”

Recent Highlights

Proprietary Portfolio

- Treated the first patient in FORWARD I and expanded the study to more than 40 sites in North America and Europe;
- Presented expanded Phase 1 data from the biopsy cohort for mirvetuximab soravtansine at the Society for Gynecologic Oncology (SGO) Annual Meeting on Women’s Cancer demonstrating that archival tumor tissue can reliably identify patients with folate receptor alpha (FR α)-positive platinum-resistant ovarian cancer and supporting the patient selection strategy for FORWARD I; and
- Delivered nine presentations at the American Association for Cancer Research (AACR) Annual Meeting demonstrating improvements to ImmunoGen’s payload and linker technologies and highlighting data with novel ADCs directed to a range of tumor targets.

Partner Programs

- Bayer completed enrollment in a registration-enabling Phase 2 study for anetumab ravtansine in mesothelioma; and
-

- Takeda initiated preclinical development with the first ADC using ImmunoGen's IGN platform directed to a solid tumor.

ASCO Presentations

ImmunoGen will report data on mirvetuximab soravtansine in poster presentations at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting on June 3, 2017:

Gynecologic Cancer: General Poster Session

Location: Hall A

Saturday, June 3, 2017, 1:15 p.m. — 4:45 p.m. CDT

- Title: Mirvetuximab soravtansine (IMGN853), a folate receptor alpha (FR α)-targeting antibody-drug conjugate (ADC), in platinum-resistant epithelial ovarian cancer (EOC) patients (pts): Activity and safety analyses in phase I pooled expansion cohorts. (Abstract No.: 5547, Poster Board No.: 369)
- Title: Safety findings from FORWARD II: A phase 1b study evaluating the folate receptor alpha (FR α)-targeting antibody-drug conjugate (ADC) mirvetuximab soravtansine (IMGN853) in combination with bevacizumab, carboplatin, pegylated liposomal doxorubicin (PLD), or pembrolizumab in patients (pts) with ovarian cancer. (Abstract No.: 5553, Poster Board No.: 375)
- Title: FORWARD I (GOG 3011): A randomized phase 3 study to evaluate the safety and efficacy of mirvetuximab soravtansine (IMGN853) versus chemotherapy in adults with folate receptor alpha (FR α)-positive, platinum-resistant epithelial ovarian cancer (EOC), primary peritoneal cancer, or primary fallopian tube cancer. (Abstract No.: TPS5607, Poster Board No.: 425b)

Additional Upcoming Events

- ImmunoGen expects to present initial Phase 1 data for IMGN779, a CD33-targeting ADC, for the treatment of acute myeloid leukemia in mid-2017. These will be the first clinical data reported with an ADC using ImmunoGen's DNA-alkylating payload.
- The Company 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.
- ImmunoGen also anticipates advancing the first development candidate under its collaboration with CytomX into preclinical development in 2017.

Financial Results

Revenues for the quarter ended March 31, 2017 were \$28.5 million, compared to \$19.7 million for the quarter ended March 31, 2016. License and milestone fees for the first quarter of 2017 included \$6 million in partner milestone payments and \$12.7 million in amortization of a non-cash fee related to the Company's license agreement with CytomX, compared with \$10 million

from partner milestone payments in the same quarter in 2016. Revenues in the first quarter of 2017 included \$7.6 million in non-cash royalty revenues, compared with \$7.4 million in non-cash royalty revenues for the same quarter in 2016. Revenues for the first quarter of 2017 also included \$1.5 million of research and development (R&D) support fees and \$0.7 million of clinical materials revenue, compared with \$1.1 million and \$1.2 million, respectively, for the same quarter in 2016.

Operating expenses for the first quarter of 2017 were \$41.4 million, compared to \$47.3 million for the same quarter in 2016. Operating expenses in the first quarter of 2017 include R&D expenses of \$32.9 million, compared to \$36.1 million for the same quarter in 2016. This change is primarily due to a workforce reduction resulting from the strategic review in September 2016, as well as decreased costs associated with manufacturing clinical materials on behalf of ImmunoGen's partners. Partially offsetting these decreases, clinical trial costs increased in the first quarter of 2017 driven primarily by studies of mirvetuximab soravtansine. Operating expenses include general and administrative expenses of \$8.1 million in the first quarter of 2017, compared to \$11.2 million in the same quarter in 2016. This decrease is primarily due to a non-cash stock compensation charge in the first quarter of 2016 resulting from the CEO transition, as well as decreased personnel expenses in the first quarter of 2017.

ImmunoGen reported a net loss of \$17.3 million, or \$0.20 per basic and diluted share, for the first quarter of 2017 compared to a net loss of \$31.9 million, or \$0.37 per basic and diluted share, for the same quarter last year.

ImmunoGen had approximately \$126.6 million in cash and cash equivalents as of March 31, 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 \$33.0 million for the first quarter of 2017, compared with \$26.1 million for the first quarter of 2016. Capital expenditures were \$0.4 million and \$3.5 million for the quarters ended March 31, 2017 and 2016, respectively.

Financial Guidance

ImmunoGen's financial guidance for 2017 remains unchanged from that issued in February 2017. ImmunoGen expects:

- Revenues between \$70 million and \$75 million, which includes \$28 million of expected upfront and milestone fees from partners;
- Operating expenses between \$175 million and \$180 million; and
- Cash and cash equivalents at December 31, 2017 between \$35 million and \$40 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 quarter 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 719-325-2452; the conference ID is 5957421. 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 May 19, 2017.

About ImmunoGen, Inc.

ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using its proprietary 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 three other clinical-stage ImmunoGen product candidates, and in programs in development by partners Amgen, Bayer, Biotest, CytomX, 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.

For Investors

Monique Allaire
Thrust IR
617-895-9511
monique@thrustir.com

For Media

Robert Stanislaro
FTI Consulting, Inc.
212-850-5657
robert.stanislaro@fticonsulting.com

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 fiscal year ended June 30, 2016 and other reports filed with the Securities and Exchange Commission.

-Financials Follow-

###

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

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2017	December 31, 2016
ASSETS		
Cash and cash equivalents	\$ 126,568	\$ 159,964
Other assets	36,753	38,900
Total assets	<u>\$ 163,321</u>	<u>\$ 198,864</u>
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities	\$ 40,367	\$ 55,776
Long-term portion of deferred revenue and other long-term liabilities	290,484	295,938
Shareholders' deficit	(167,530)	(152,850)
Total liabilities and shareholders' deficit	<u>\$ 163,321</u>	<u>\$ 198,864</u>

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2017	2016
Revenues:		
License and milestone fees	\$ 18,730	\$ 10,077
Non-cash royalty revenue	7,613	7,380
Research and development support	1,478	1,059
Clinical materials revenue	678	1,198
Total revenues	<u>28,499</u>	<u>19,714</u>
Expenses:		
Research and development	32,888	36,094
General and administrative	8,119	11,235
Restructuring charge	386	—
Total operating expenses	<u>41,393</u>	<u>47,329</u>
Loss from operations	(12,894)	(27,615)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(3,575)	(4,972)
Interest expense on convertible bonds	(1,125)	—
Other income, net	249	659
Net loss	<u>\$ (17,345)</u>	<u>\$ (31,928)</u>
Net loss per common share, basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.37)</u>
Weighted average common shares outstanding, basic and diluted	<u>87,160</u>	<u>87,035</u>