
**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): **February 8, 2019**

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 February 8, 2019, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the company's financial results for the quarter and year ended December 31, 2018. The press release announcing financial results for the quarter and year ended December 31, 2018 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 February 8, 2019 |

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: February 8, 2019

/s/ David G. Foster

David G. Foster
Vice President, Finance



ImmunoGen Reports Recent Progress and 2018 Operating Results

Top-Line Data from Phase 3 FORWARD I Mirvetuximab Soravtansine Study on Track for First Half of 2019

Encouraging Clinical Data from Novel IGN Pipeline Highlighted in Two Oral Presentations at ASH 2018

Sale of Kadcyła® Royalty Tail for \$65 Million Further Strengthens Financial Position

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

Waltham, Mass. — February 8, 2019 — ImmunoGen, Inc., (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today reviewed recent progress and operating results for the quarter and year ended December 31, 2018.

“We generated significant momentum in the business during 2018, led by the completion of enrollment in FORWARD I, our registration study for mirvetuximab soravtansine in platinum-resistant ovarian cancer; the publication of combination data in over 100 patients to support label expansion; and the advancement of our earlier-stage portfolio,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “On the strength of this performance, we enter 2019 poised to deliver on a number of important catalysts for the company, including top-line results from FORWARD I in the first half of the year, the potential BLA and MAA submissions for mirvetuximab monotherapy in the second half of the year, and additional combination data from our triplet in platinum-sensitive disease. Beyond our lead program, we expect to report data from expansion studies in AML and BPDCN with our programs targeting hematological malignancies and to file an IND before year-end for IMG936, an ADAM9-targeting ADC being developed in collaboration with MacroGenics. Finally, with the benefit of the sale of the Kadcyła royalty tail, we start the year with roughly \$325 million on the balance sheet to support our development and pre-commercial activities as we transition to a fully-integrated company.”

RECENT PROGRESS

Mirvetuximab Soravtansine

- Validation runs were successfully completed and commercial drug product is now in inventory.
- The Premarket Approval (PMA) submission for the folate receptor alpha companion diagnostic was initiated.
- Patient enrollment completed ahead of schedule in the FORWARD II triplet combination cohort evaluating mirvetuximab plus carboplatin and Avastin® (bevacizumab) in patients with recurrent platinum-sensitive ovarian cancer.
- Initial safety and preliminary anti-tumor activity from the FORWARD II expansion cohort assessing mirvetuximab in combination with Merck’s anti-PD-1 therapy, Keytruda® (pembrolizumab), were presented at the European Society for Medical Oncology (ESMO) 2018 Congress in October. Data from this cohort confirm the activity of mirvetuximab in heavily pretreated platinum-resistant ovarian cancer, with a trend toward longer duration of response with the combination than would be expected for mirvetuximab monotherapy. Maturing data from this cohort will guide further development of this novel combination.

IGN Programs and Early-Stage Pipeline

- Both IGN programs received Orphan Drug Designation in acute myeloid leukemia (AML).
 - Encouraging initial data from the Phase 1 study of IMG632 in patients with relapsed or refractory adult AML and blastic plasmacytoid dendritic cell neoplasm (BPDCN) were presented at the American Society of Hematology (ASH) Annual Meeting in December. IMG632 displayed anti-leukemia activity across all dose levels tested and a tolerable safety profile at doses up to 0.3 mg/kg. Enrollment in expansion cohorts is ongoing to identify the recommended Phase 2 dose and schedule for both AML and BPDCN.
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- Updated data from the IMG779 Phase 1 dose finding study in AML patients were also presented at ASH. These data show that IMG779 continues to display a tolerable safety profile with repeat dosing across a wide range of doses on the two schedules explored in patients with relapsed AML, with anti-leukemia activity seen in both schedules. Enrollment is ongoing to identify the recommended Phase 2 dose and schedule.
- IND-enabling activities were initiated during the quarter for IMG936, a novel ADAM9-targeting ADC being developed in collaboration with MacroGenics.
- Multiple abstracts highlighting platform innovations were submitted for presentation at the 2019 Annual Meeting of the American Association for Cancer Research.

Operational Updates

- Commercial planning and launch readiness activities for mirvetuximab have been initiated to support a potential launch in 2020.
- Earlier this month, ImmunoGen announced the sale of residual rights to receive royalty payments on commercial sales of Kadcyca (ado-trastuzumab emtansine) to the Ontario Municipal Employees Retirement System (OMERS), the defined benefit pension plan for municipal employees in the Province of Ontario, Canada, for \$65 million.

ANTICIPATED 2019 EVENTS

- Report top-line results from Phase 3 FORWARD I trial of mirvetuximab in platinum-resistant ovarian cancer in the first half of 2019, followed by full FORWARD I data presentation at a medical meeting;
- Assuming a positive readout of FORWARD I, submit Biologics License Application (BLA) and Marketing Authorization Application (MAA) for mirvetuximab for the treatment of women with platinum-resistant ovarian cancer in 2H 2019;
- Enroll FORWARD II Avastin cohort in platinum-agnostic ovarian cancer;
- Present initial FORWARD II triplet and mature doublet expansion cohort data;
- Present updated IMG632 data with additional AML and BPDCN patients, and establish the recommended Phase 2 dose and schedule;
- Initiate IMG632 combination studies;
- Establish IMG779 recommended Phase 2 dose and schedule for combination studies in AML; and
- Submit an IND for IMG936 before the end of 2019.

FINANCIAL RESULTS

Revenues for the year ended December 31, 2018 were \$53.8 million, compared with \$115.4 million for the year ended December 31, 2017. License and milestone fees of \$15.3 million for 2018 included \$13.8 million of recognized upfront fees previously received from partners and \$1.5 million in partner milestone payments. This was compared to license and milestone fees of \$79.5 million for 2017, which included a \$30 million paid-up license fee related to an amendment to the Company's collaboration and license agreement with Sanofi, \$29.5 million related to the sale and transfer of the Company's IMG529 asset to Debiopharm, \$7 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. Revenues for 2018 included \$32.5 million in non-cash royalty revenues, compared with \$28.1 million for 2017. Revenues for 2018 also included \$1.4 million of research and development (R&D) support fees and \$4.6 million of clinical materials revenue, compared with \$3.5 million and \$4.4 million, respectively, for 2017.

Operating expenses for 2018 were \$214.3 million, compared with \$174.4 million for 2017. The increase was driven by R&D expenses, which were \$173.9 million for 2018, compared with \$139.7 million for 2017. This increase was primarily due to higher external manufacturing costs and third-party service fees in support of commercial validation for mirvetuximab soravtansine, along with higher clinical trial costs related to the FORWARD I, FORWARD II, and IMG632 studies and, to a lesser extent, an increase in stock-based compensation. General and administrative expenses for 2018 increased to \$36.7 million, compared to \$33.9 million for 2017, primarily due to increased third-party service fees and stock-based compensation. Operating expenses for 2018 also included a \$3.7 million restructuring charge due to the previously announced decommissioning of the Company's Norwood facility, compared to a \$0.8 million charge in 2017 related to a loss recorded on leased office space.

ImmunoGen reported a net loss of \$167.9 million, or \$1.20 per basic and diluted share, for 2018, compared with a net loss of \$96.0 million, or \$0.98 per basic and diluted share, for 2017. Weighted average shares outstanding increased to 139.9 million in 2018 from 98.1 million in 2017.

ImmunoGen had \$262.3 million in cash and cash equivalents as of December 31, 2018, compared with \$267.1 million as of December 31, 2017, and had \$2.1 million of convertible debt outstanding in each period. Cash used in operations was \$166.4 million for 2018, compared with cash provided from operations of \$7.6 million for 2017. The prior period benefited from a \$75 million upfront payment received from Jazz Pharmaceuticals, and \$59.5 million of fees received from Sanofi and Debiopharm. Capital expenditures were \$5.2 million and \$1.1 million for 2018 and 2017, respectively.

FINANCIAL GUIDANCE

For 2019, ImmunoGen expects:

- cash and cash equivalents at December 31, 2019 to be between \$135 million and \$140 million;
- revenues between \$40 million and \$45 million; and
- operating expenses between \$265 and \$270 million.

ImmunoGen expects that its current cash combined with the expected cash receipts from partners and collaborators will enable the Company to fund its operations at least a year beyond the release of top-line results from the Phase 3 FORWARD I trial, which are expected in the first half 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 323-794-2093; the conference ID is 6271602. 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 February 22, 2019.

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." Our lead product candidate, mirvetuximab soravtansine, is in a Phase 3 study for folate receptor alpha (FR α)-positive platinum-resistant ovarian cancer, and in Phase 1b/2 testing in combination regimens. Our novel IGN candidates for hematologic malignancies, IMG779 and IMG632, are in Phase 1 studies.

Learn more about who we are, what we do, and how we do it at www.immunogen.com.

FORWARD-LOOKING STATEMENTS

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 and operating expenses for the twelve months ending December 31, 2019; its cash and marketable securities as of December 31, 2019; 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 year ended December 31, 2017 and other reports filed with the Securities and Exchange Commission.

INVESTOR RELATIONS CONTACT

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

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

| | December 31, 2018 | December 31, 2017 |
|--|------------------------------|------------------------------|
| ASSETS | | |
| Cash and cash equivalents | \$ 262,252 | \$ 267,107 |
| Other assets | 33,499 | 27,569 |
| Total assets | <u>\$ 295,751</u> | <u>\$ 294,676</u> |
| LIABILITIES AND SHAREHOLDERS' DEFICIT | | |
| Current portion of deferred revenue | \$ 317 | \$ 1,405 |
| Other current liabilities | 69,743 | 54,365 |
| Long-term portion of deferred revenue | 80,485 | 93,752 |
| Other long-term liabilities | 133,264 | 163,049 |
| Shareholders' equity (deficit) | 11,942 | (17,895) |
| Total liabilities and shareholders' equity (deficit) | <u>\$ 295,751</u> | <u>\$ 294,676</u> |

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

| | Three Months Ended December 31, | | Year Ended December 31, | |
|--|------------------------------------|--------------------|----------------------------|--------------------|
| | 2018 | 2017 | 2018 | 2017 |
| Revenues: | | | | |
| License and milestone fees | \$ 1,747 | \$ 29,580 | \$ 15,280 | \$ 79,469 |
| Non-cash royalty revenue | 9,651 | 7,587 | 32,524 | 28,142 |
| Research and development support | 218 | 452 | 1,377 | 3,482 |
| Clinical materials revenue | 2,170 | 1,829 | 4,635 | 4,354 |
| Total revenues | 13,786 | 39,448 | 53,816 | 115,447 |
| Expenses: | | | | |
| Research and development | 43,111 | 39,843 | 173,886 | 139,739 |
| General and administrative | 9,722 | 9,048 | 36,716 | 33,911 |
| Restructuring charge | 406 | 393 | 3,693 | 779 |
| Total operating expenses | 53,239 | 49,284 | 214,295 | 174,429 |
| Loss from operations | (39,453) | (9,836) | (160,479) | (58,982) |
| Non-cash interest expense on liability related to sale of future royalty & convertible bonds | (2,428) | (3,221) | (10,631) | (13,682) |
| Non-cash debt conversion expense | — | (724) | — | (22,915) |
| Interest expense on convertible bonds | (25) | (28) | (95) | (3,040) |
| Other income, net | 1,077 | 691 | 3,332 | 2,607 |
| Net loss | \$ (40,829) | \$ (13,118) | \$ (167,873) | \$ (96,012) |
| Net loss per common share, basic and diluted | \$ (0.28) | \$ (0.11) | \$ (1.20) | \$ (0.98) |
| Weighted average common shares outstanding, diluted | 147,287 | 124,583 | 139,946 | 98,068 |