

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 14, 2020

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 February 14, 2020, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the company's financial results for the quarter and year ended December 31, 2019. The press release announcing financial results for the quarter and year ended December 31, 2019 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 February 14, 2020
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: February 14, 2020

/s/ David G. Foster

David G. Foster
Vice President, Finance

ImmunoGen Reports Recent Progress and 2019 Financial Results

Accelerated Approval Pathway Defined for Mirvetuximab Soravtansine in Ovarian Cancer; Pivotal SORAYA Trial Expected to Enroll First Patient in Q1 2020

Phase 3 Confirmatory MIRASOL Trial for Mirvetuximab Enrolling Patients

Updated IMG632 AML and BPDCN Monotherapy Data Presented at ASH

\$97.6 Million Net Proceeds from Public Offering Extends Cash Runway to Second Half of 2022

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

Waltham, MA – February 14, 2020 – **ImmunoGen, Inc.**, (Nasdaq: IMG632), 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 and year ended December 31, 2019.

“Following the results of FORWARD I, we moved decisively to restructure the business to reduce our costs, prioritized our portfolio to focus on our most promising programs, and worked constructively with FDA to define an accelerated path to approval for mirvetuximab,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “With the benefit of these steps, we have emerged from a challenging year with significant momentum driven by the start of our registration program for mirvetuximab in platinum-resistant ovarian cancer and continued progress with our portfolio of early-stage products. In particular, we have enrolled the first patient in the confirmatory MIRASOL Phase 3 trial for mirvetuximab, presented clinical data at ASH in December demonstrating IMG632’s encouraging anti-tumor activity and favorable tolerability in patients with AML and BPDCN, and, most recently, raised roughly \$98 million in a follow-on offering to strengthen our balance sheet.”

Enyedy added, “We enter 2020 with a number of important upcoming milestones to drive value in the business. For mirvetuximab, these include opening our pivotal SORAYA trial in the first quarter, continuing to enroll MIRASOL, initiating an additional combination study in platinum-sensitive disease, and presenting data from our platinum-agnostic and platinum-sensitive combination studies. Building upon the encouraging data we reported in 2019, we will continue to advance IMG632 in the clinic and look forward to presenting BPDCN and MRD+ monotherapy and AML combination data this year. In addition, we expect the IND for IMG936, our novel ADAM9-targeting ADC, to be filed during the first half of the year. With these catalysts ahead, we look forward to a productive next twelve months.”

RECENT PROGRESS

- Received guidance from the U.S. Food and Drug Administration (FDA) that SORAYA, a new single-arm study in platinum-resistant ovarian cancer, could support accelerated approval for mirvetuximab.
 - Enrolled the first patient in our confirmatory Phase 3 MIRASOL trial.
 - Presented preclinical combination data and updated clinical monotherapy data for IMG632 with additional patients enrolled in acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN) expansion cohorts at the American Society of Hematology (ASH) Annual Meeting in December.
 - Continued enrollment for IMG632 monotherapy in Phase 1 expansion cohorts in patients with AML, BPDCN, relapsed acute lymphocytic leukemia (ALL), and minimal residual disease positive (MRD+) AML patients following frontline induction therapy.
 - Advanced IMG632 combination therapy studies with Vidaza® (azacitidine) and Venclexta® (venetoclax) in relapsed/refractory unfit AML patients.
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- Progressed investigational new drug (IND)-enabling activities for IMGC936, a novel ADAM9-targeting ADC in co-development with MacroGenics.
- Outlicensed our epithelial cell adhesion molecule (EpCAM)-targeting Probod[™]-drug conjugate to CytomX in exchange for an upfront fee and milestone and royalty payments.
- Raised \$97.6 million in a follow-on offering completed in January.

ANTICIPATED 2020 EVENTS

- Initiate pivotal SORAYA trial in the first quarter of 2020 and continue enrollment in the confirmatory Phase 3 MIRASOL trial.
- Open an additional platinum-sensitive investigator sponsored trial evaluating mirvetuximab in combination with carboplatin.
- Present initial data from the Phase 1b FORWARD II platinum-agnostic doublet cohort evaluating mirvetuximab in combination with Avastin[®] (bevacizumab) in mid-2020 and updated data from the FORWARD II platinum-sensitive triplet cohort evaluating mirvetuximab in combination with carboplatin and bevacizumab in the fall of 2020.
- Continue enrollment with IMGN632 monotherapy in relapsed AML, ALL, BPDCN, and MRD+ AML expansion cohorts and in combinations in AML.
- Present IMGN632 BPDCN and AML combination and MRD+ monotherapy data at ASH in December.
- File IND for IMGC936 in the first half of 2020.
- Transition next generation anti-folate receptor alpha (FR α) ADC, IMGN151, to pre-clinical development in mid-2020.

FINANCIAL RESULTS

Total revenues in the fourth quarter and year ended December 31, 2019 increased to \$44.9 million and \$82.3 million, respectively, compared to \$13.4 million and \$53.4 million for the same periods in 2018. Revenues are comprised of the following components:

- *License and milestone fees:* License and milestone fees of \$34.8 million for the year ended 2019, of which \$29.6 million was recorded in the fourth quarter, included \$14.5 million in amortization of a \$75 million upfront fee previously received under the Company's collaboration agreement with Jazz, \$7.3 million of a \$7.5 million fee recognized pursuant to a license agreement executed with CytomX in December 2019, and \$12.7 million in partner milestones. Of these amounts noted, \$15.2 million of related cash will be received in 2020. 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.
- *Non-cash royalty revenue:* Non-cash royalty revenue in the fourth quarter and year ended December 31, 2019 increased to \$15.3 million and \$47.4 million, respectively, compared to \$9.3 million and \$32.2 million for the same periods in 2018.

Research and development expenses were \$26.1 million for the quarter ended December 31, 2019 compared to \$43.7 million for the quarter ended December 31, 2018, and \$114.5 million for the year ended December 31, 2019 compared to \$174.5 million for the year ended December 31, 2018. The decreases in both periods are primarily due to: (i) lower expenses resulting from the restructuring of the business at the end of the second quarter of 2019 and the closing of our manufacturing facility at the end of 2018, including decreases in personnel, facility, and third-party research expenses; (ii) lower external manufacturing costs driven by activity to support commercial validation of mirvetuximab in the prior year periods; and, (iii) decreased clinical trial expenses for the year ended December 31, 2019 driven by lower activity in the FORWARD I Phase 3 clinical trial; however, clinical trial expenses for the fourth quarter of 2019 increased compared to the fourth quarter of 2018 driven by expenses incurred to initiate the MIRASOL and IMGN632 combination studies.

General and administrative expenses were flat at \$9.8 million for the fourth quarter of 2019 and 2018, and \$38.5 million for the year ended December 31, 2019 compared to \$36.7 million for the year ended December 31, 2018. The increase year over year is primarily due to a higher allocation of facility-related expenses for excess laboratory and office space, partially offset by lower personnel expenses resulting from the restructuring of the business. Similar variances occurred quarter over quarter, but were further offset by lower stock compensation expense driven largely by stock options forfeited in the fourth quarter of 2019.

Restructuring charge of \$0.5 million and \$21.4 million recorded in the fourth quarter and year ended December 31, 2019, respectively, related to the restructuring of the business at the end of the second quarter of 2019, compared to \$0.4 million and \$3.7 million recorded in the same periods in 2018 related to the decommissioning of the Norwood facility.

Net income for the fourth quarter of 2019 was \$4.8 million, or \$0.03 per basic and diluted share, compared to a net loss of \$(41.8) million, or \$(0.28) per basic and diluted share, for the fourth quarter of 2018. Net loss for the year ended December 31, 2019 was \$(104.1) million, or \$(0.70) per basic and diluted share, compared to a net loss of \$(168.8) million, or \$(1.21) per basic and diluted share.

ImmunoGen had \$176.2 million in cash and cash equivalents as of December 31, 2019, compared with \$262.3 million as of December 31, 2018, and had \$2.1 million of convertible debt outstanding in each period. Cash used in operations was \$88.4 million for the year ended December 31, 2019, compared with cash used in operations of \$166.4 million for the year ended December 31, 2018. The current year benefited from \$65.2 million of net proceeds generated from the sale of the Company's residual rights to Kadcyla[®] (ado-trastuzumab emtasine) royalties in January 2019. Capital expenditures, net of proceeds from the sale of equipment, were \$0.5 million and \$5.2 million for 2019 and 2018, respectively.

In January 2020, pursuant to a public offering, the Company sold an aggregate of 24,523,750 shares of its common stock, with net proceeds to the Company of \$97.6 million, after deducting underwriting discounts and estimated offering expenses.

FINANCIAL GUIDANCE

For 2020, ImmunoGen expects:

- revenues between \$60 million and \$65 million;
- operating expenses between \$165 million and \$170 million; and
- cash and cash equivalents at December 31, 2020 to be between \$170 million and \$175 million.

ImmunoGen expects that its current cash, inclusive of the proceeds generated from the recent public offering and anticipated cash receipts from partners, will fund operations into the second half of 2022.

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, dial (877) 621-5803; the conference ID is 3989656. The call may also be accessed through the Investors and Media section of immunogen.com. Following the call, a replay will be available at the same location.

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.

Avastin[®], Vidaza[®], Venclexta[®], and Kadcyla[®] are registered trademarks of their respective owners.

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, 2020; its cash and marketable securities as of December 31, 2020 the occurrence, timing, and outcome of potential pre-clinical, clinical, and regulatory events related to the Company's product candidates; and the presentation of pre-clinical and clinical data on the Company's 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 the Company's clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense, and results of pre-clinical studies, clinical trials, and regulatory processes; the Company's ability to financially support its product programs; and other factors more fully described in ImmunoGen's Annual Report on Form 10-K for the year ended December 31, 2018 and other reports filed with the Securities and Exchange Commission.

INVESTOR RELATIONS AND MEDIA CONTACTS

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

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	December 31, 2019	December 31, 2018
ASSETS		
Cash and cash equivalents	\$ 176,225	\$ 262,252
Other assets	59,437	33,129
Total assets	<u>\$ 235,662</u>	<u>\$ 295,381</u>
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
Current portion of deferred revenue	\$ 309	\$ 317
Other current liabilities	77,101	70,343
Long-term portion of deferred revenue	127,123	80,485
Other long-term liabilities	107,250	133,264
Shareholders' (deficit) equity	<u>(76,121)</u>	<u>10,972</u>
Total liabilities and shareholders' (deficit) equity	<u>\$ 235,662</u>	<u>\$ 295,381</u>

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenues:				
Non-cash royalty revenue	\$ 15,313	\$ 9,281	\$ 47,415	\$ 32,154
License and milestone fees	29,551	1,747	34,788	15,280
Research and development support	-	218	68	1,377
Clinical materials revenue	-	2,170	-	4,635
Total revenues	44,864	13,416	82,271	53,446
Expenses:				
Research and development	26,055	43,681	114,522	174,456
General and administrative	9,803	9,752	38,489	36,746
Restructuring charge	512	406	21,433	3,693
Total operating expenses	36,370	53,839	174,444	214,895
Income (loss) from operations	8,494	(40,423)	(92,173)	(161,449)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(5,354)	(2,428)	(16,879)	(10,631)
Interest expense on convertible bonds	(24)	(25)	(95)	(95)
Other income, net	1,698	1,077	5,014	3,332
Net income (loss)	\$ 4,814	\$ (41,799)	\$ (104,133)	\$ (168,843)
Basic and diluted net income (loss) per common share	\$ 0.03	\$ (0.28)	\$ (0.70)	\$ (1.21)
Basic and diluted weighted average common shares outstanding	148,809	147,287	148,311	139,946