

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 12, 2021

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 12, 2021, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the company's financial results for the quarter and year ended December 31, 2020. The press release announcing financial results for the quarter and year ended December 31, 2020 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 12, 2021
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 12, 2021

/s/ David G. Foster

David G. Foster
Vice President, Finance

ImmunoGen Reports Recent Progress and 2020 Financial Results

Top-Line Data from Pivotal SORAYA Trial for Mirvetuximab Soravtansine in Ovarian Cancer Expected in Q3 2021; BLA to be Submitted by Year-End

Full Approval Pathway for IMG632 in BPDCN Aligned with FDA; Updated Phase 1/2 Data in BPDCN Presented at ASH

Balance Sheet Funds Operations into the Second Half of 2022

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

Waltham, MA – February 12, 2021 – **ImmunoGen Inc.** (Nasdaq: IMGN), 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, 2020.

“Despite the challenges of the pandemic, 2020 was a transformative year for ImmunoGen, as we adjusted to new ways of working, accelerated our portfolio, strengthened our management team and balance sheet, and positioned the business for two potential product launches next year,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “Within our portfolio, we advanced accrual in the pivotal SORAYA and confirmatory MIRASOL trials for mirvetuximab soravtansine in patients with ovarian cancer to support our projected timelines for top-line data and regulatory submissions. In addition, we established a second registration program with our CD123-targeting ADC, IMG632, for which we received Breakthrough Therapy designation and aligned with FDA on a path to full approval in BPDCN. Furthermore, we began dosing patients in the Phase 1 study of IMGC936, our first-in-class ADAM9-targeting ADC for solid tumors, and transitioned IMG151, our next-generation FR α -targeting ADC, into preclinical development. Finally, through a combination of business development and activity under our ATM facility, we added over \$140 million to our balance sheet in the fourth quarter.”

Enyedy continued, “With the benefit of our progress in 2020, we enter this year with significant momentum and strong prospects for the business. For mirvetuximab, these include completing enrollment in SORAYA and reporting top-line pivotal data in the third quarter, followed by a planned BLA submission by the end of the year. With IMG632, we expect top-line pivotal data in BPDCN in 12 to 18 months and anticipate sharing data from our Phase 1b/2 study of IMG632 in combination with azacitidine and/or venetoclax in AML patients at ASH in December. We also anticipate completing dose escalation in the clinical study of IMGC936, with initial data late this year or early 2022. Finally, we expect to submit the IND for IMG151 by year-end. Taken together, our pivotal programs, experienced management team, and strong balance sheet position us well to execute on our strategy and transition ImmunoGen to a fully-integrated oncology company with two products on the market in 2022.”

RECENT PROGRESS

- Continued patient enrollment in the pivotal SORAYA and confirmatory MIRASOL trials.
 - Advanced our partnership with Huadong Medicine, having received acceptance of the investigational new drug (IND) application for mirvetuximab in China from the National Medical Products Administration (NMPA).
 - Aligned with the US Food and Drug Administration (FDA) on a path to full approval for IMG632, amending our ongoing 801 Phase 1/2 study with a new pivotal cohort of up to 20 frontline blastic plasmacytoid dendritic cell neoplasm (BPDCN) patients.
 - Presented updated safety and efficacy findings from the Phase 1/2 expansion study of IMG632 in patients with relapsed/refractory (R/R) BPDCN during an oral session at the American Society of Hematology (ASH) Annual Meeting in December. Our collaborators at MD Anderson Cancer Center also presented preclinical data at ASH in R/R acute myeloid leukemia (AML) that further support the combination of IMG632 with Vidaza[®] (azacitidine) and Venclaxta[®] (venetoclax).
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- Advanced patient accrual in the Phase 1 dose-escalation study evaluating IMG936, our novel ADAM9-targeting ADC in co-development with MacroGenics.

UPCOMING EVENTS

- Complete patient enrollment in SORAYA, with top-line pivotal data expected in the third quarter of 2021, and submit the biologics license application (BLA) by the end of 2021 to support potential accelerated approval in 2022.
- Complete patient enrollment in MIRASOL, with top-line data expected in the first half of 2022.
- Present mature data from the Phase 1b FORWARD II cohort evaluating mirvetuximab in combination with Avastin® (bevacizumab) in platinum agnostic, recurrent ovarian cancer at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting.
- Support initiation of two investigator-sponsored trials of mirvetuximab plus carboplatin, including a randomized Phase 2 study in recurrent platinum-sensitive ovarian cancer and a neo-adjuvant study.
- Enroll patients in the pivotal cohort of the 801 Phase 1/2 study of IMG632 in frontline BPDCN patients and generate top-line data in 12 to 18 months.
- Advance the 802 Phase 1b/2 study of IMG632 in combination with azacitidine and venetoclax in R/R and frontline AML patients and as a monotherapy in minimal residual disease positive (MRD+) AML following frontline induction therapy.
- Present updated R/R BPDCN and initial AML combination data for IMG632 at ASH 2021.
- Complete dose escalation and move to expansion cohorts in the Phase 1 study evaluating IMG936, with initial data anticipated by the end of 2021 or early 2022.
- Submit the investigational new drug (IND) application for IMG151 by the end of 2021.

FINANCIAL RESULTS

Total revenues in the fourth quarter and year ended December 31, 2020 increased to \$85.8 million and \$132.3 million, respectively, compared to \$44.9 million and \$82.3 million for the same periods in 2019. Revenues are comprised of the following components:

- *License and milestone fees:* License and milestone fees of \$63.7 million for the year ended 2020, of which \$62.4 million was recorded in the fourth quarter, included recognition of \$60.5 million of the upfront fee previously received under the Company's collaboration agreement with Jazz Pharmaceuticals, and \$3.2 million in upfront fees previously received from other partners. License and milestone fees of \$34.8 million for 2019 included recognition of \$22.1 million in upfront fees previously received from partners and \$12.7 million in partner milestone payments.
- *Non-cash royalty revenue:* Non-cash royalty revenue in the fourth quarter and year ended December 31, 2020 increased to \$23.4 million and \$68.5 million, respectively, compared to \$15.3 million and \$47.4 million for the same periods in 2019 due to rising global sales of Kadcyra® during both periods in 2020.

Research and development expenses were \$39.6 million for the quarter ended December 31, 2020 compared to \$26.1 million for the quarter ended December 31, 2019, and \$114.6 million for the year ended December 31, 2020 compared to \$114.5 million for the year ended December 31, 2019. The increase in the current quarter was due to greater external manufacturing costs related to the potential commercial launch of mirvetuximab and clinical trials costs driven by advancement of the SORAYA and MIRASOL studies.

General and administrative expenses were flat at \$9.7 million and \$9.8 million for the quarters ended December 31, 2020 and 2019, respectively, and \$38.6 million and \$38.5 million for the years ended December 31, 2020 and 2019, respectively.

Restructuring charges of \$1.5 million and \$21.4 million were recorded in the years ended December 31, 2020 and 2019, respectively, related to the restructuring of the business at the end of the second quarter of 2019, with the current year charge comprised substantially of retention costs.

Net income for the fourth quarter of 2020 was \$31.4 million, or \$0.16 per diluted share, compared to net income of \$4.8 million, or \$0.03 per diluted share, for the fourth quarter of 2019. Net loss for the year ended December 31, 2020 was \$(44.4) million, or \$(0.25) per diluted share, compared to a net loss of \$(104.1) million, or \$(0.70) per diluted share, for the year ended December 31, 2019.



ImmunoGen had \$293.9 million in cash and cash equivalents as of December 31, 2020, compared with \$176.2 million as of December 31, 2019, and had \$2.1 million of convertible debt outstanding in each period. Cash used in operations was \$78.6 million for the year ended December 31, 2020 compared with \$88.4 million for the year ended December 31, 2019. Net proceeds from the sale of equipment were \$0.5 million for 2020 compared with net capital expenditures of \$(0.5) million for 2019.

During the quarter ended December 31, 2020, the Company sold approximately 20 million shares of its common stock through its At-the-Market (ATM) facility, generating gross proceeds to the Company of approximately \$100 million. In January 2021, the Company sold an additional 4.5 million shares of its common stock through its ATM facility, generating additional gross proceeds of approximately \$35 million.

FINANCIAL GUIDANCE

For 2021, ImmunoGen expects:

- revenues between \$65 million and \$75 million;
- operating expenses between \$200 million and \$210 million; and
- cash and cash equivalents at December 31, 2021 to be between \$140 million and \$150 million.

ImmunoGen expects that its current cash, inclusive of the net proceeds generated from recent sales through its ATM facility, will fund operations into the second half of 2022.

Revenue guidance includes the assumption that a portion of the upfront license fee from Huadong Medicine will be recognized in 2021 beginning with the delivery of the first clinical supply of mirvetuximab to support development in China.

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 1666147. 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®, Kadcyła®, Vidaza®, and Venclexta® 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, 2021; its cash and cash equivalents as of December 31, 2021; the occurrence, timing, and outcome of potential preclinical, clinical, and regulatory events related to the Company's product candidates; and the presentation of preclinical 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 preclinical 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; the Company's ability to financially support its product programs; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and the resulting impact on ImmunoGen's industry and business; and other factors more fully described under “Risk Factors” set forth on Exhibit 99.1 to ImmunoGen's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 18, 2020 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, 2020	December 31, 2019
ASSETS		
Cash and cash equivalents	\$ 293,856	\$ 176,225
Other assets	61,216	59,037
Total assets	<u>\$ 355,072</u>	<u>\$ 235,262</u>
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current portion of deferred revenue	\$ 29,249	\$ 309
Other current liabilities	93,074	77,101
Long-term portion of deferred revenue	80,860	127,123
Other long-term liabilities	62,319	106,850
Shareholders' equity (deficit)	89,570	(76,121)
Total liabilities and shareholders' equity (deficit)	<u>\$ 355,072</u>	<u>\$ 235,262</u>



CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Revenues:				
Non-cash royalty revenue	\$ 62,417	\$ 29,551	\$ 63,742	\$ 34,788
License and milestone fees	23,370	15,313	68,529	47,415
Research and development support	11	-	28	68
Total revenues	85,798	44,864	132,299	82,271
Expenses:				
Research and development	39,578	26,055	114,592	114,522
General and administrative	9,738	9,803	38,600	38,489
Restructuring charge	(37)	512	1,487	21,433
Total operating expenses	49,279	36,370	154,679	174,444
Income (loss) from operations	36,519	8,494	(22,380)	(92,173)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(5,679)	(5,354)	(23,107)	(16,879)
Interest expense on convertible bonds	(24)	(24)	(95)	(95)
Other income, net	572	1,698	1,210	5,014
Net income (loss)	\$ 31,388	\$ 4,814	\$ (44,372)	\$ (104,133)
Net income (loss) per common share - basic	\$ 0.17	\$ 0.03	\$ (0.25)	\$ (0.70)
Net income (loss) per common share - diluted	\$ 0.16	\$ 0.03	\$ (0.25)	\$ (0.70)
Shares used in computation of per share amounts - basic	188,681	148,809	176,153	148,311
Shares used in computation of per share amounts - diluted	191,089	150,605	176,153	148,311