

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): November 6, 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 November 6, 2020, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the company's financial results for the quarter and nine months ended September 30, 2020. The press release announcing financial results for the quarter and nine months ended September 30, 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 November 6, 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: November 6, 2020

/s/ David G. Foster

David G. Foster
Vice President, Finance

ImmunoGen Reports Recent Progress and Third Quarter 2020 Financial Results

Partnership with Huadong Medicine Accelerates Development and Commercialization of Mirvetuximab Soravtansine in Greater China

Encouraging Anti-Tumor Activity and Tolerability Data from FORWARD II Triplet Cohort Evaluating Mirvetuximab in Combination with Carboplatin and Avastin® in Platinum-Sensitive Ovarian Cancer Presented at ESMO

FDA Breakthrough Therapy Designation Received for IMG632 in Relapsed or Refractory BPDCN

First Patient Enrolled in Phase 1 Trial Evaluating ADAM9-Targeting ADC, IMG936, in Solid Tumors

Strengthened Balance Sheet Expected to Fund Operations into the Second Half of 2022

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

Waltham, MA - November 6, 2020 - **ImmunoGen, Inc.**, (Nasdaq: IMG6) 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 ended September 30, 2020.

“We have generated significant momentum over the last several months, achieving a number of important milestones across the business,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “Our collaboration with Huadong Medicine accelerates access to mirvetuximab for ovarian cancer patients in Greater China with an ideal partner who brings extensive regional and oncology development and commercialization experience and capabilities. Beyond Greater China, we continue to prioritize enrollment in our pivotal trials and remain on track to report top-line data in the third quarter of 2021 for SORAYA and the first half of 2022 for MIRASOL.”

Enyedy continued, “At ESMO in September, we shared final data from our FORWARD II triplet cohort, which demonstrated the encouraging efficacy and favorable tolerability of mirvetuximab in combination with carboplatin and Avastin® in FRα-positive recurrent, platinum-sensitive ovarian cancer. We are working to define the best path to label expansion for our combination regimens to benefit patients in earlier lines of therapy and establish mirvetuximab as the agent of choice to pair with other agents in ovarian cancer. On the regulatory front, we were pleased to receive FDA Breakthrough Therapy designation for IMG632 in relapsed or refractory BPDCN, confirming the high unmet need for safe and effective therapies for this rare, aggressive cancer. We continue to advance multiple cohorts with IMG632 and look forward to presenting updated monotherapy BPDCN expansion data in an oral presentation at ASH. Furthermore, we were pleased to enroll the first patient in our Phase 1 trial evaluating IMG936, our ADAM9-targeting ADC in co-development with MacroGenics. Finally, we have further strengthened our balance sheet via our At-the-Market facility and business development activities and now expect to fund operations into the second half of 2022.”

RECENT PROGRESS

- Entered into an exclusive collaboration to develop and commercialize mirvetuximab soravtansine in mainland China, Hong Kong, Macau, and Taiwan (Greater China) for an upfront payment of \$40 million, with the potential to receive additional milestone payments of up to \$265 million as certain development, regulatory, and commercial objectives are achieved, as well as low double-digit to high
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teen royalties as a percentage of mirvetuximab commercial sales. Lazard acted as financial advisor and Ropes & Gray LLP acted as legal advisor to ImmunoGen in support of this transaction.

- Continued site activation and patient enrollment in the pivotal SORAYA and confirmatory MIRASOL trials.
- Presented mature data from the FORWARD II platinum-sensitive triplet cohort evaluating mirvetuximab in combination with carboplatin and Avastin® (bevacizumab) at the European Society for Medical Oncology (ESMO) Congress.
- Received Breakthrough Therapy designation from the US Food and Drug Administration (FDA) for IMG632 in relapsed or refractory blastic plasmacytoid dendritic cell neoplasm (BPDCN).
- Continued to advance multiple cohorts with IMG632, including monotherapy expansion in BPDCN and minimal residual disease positive (MRD+) acute myeloid leukemia (AML) following frontline induction therapy and combinations with Vidaza® (azacitidine) and Venclexta® (venetoclax) in relapsed or refractory AML patients.
- Enrolled first patient in a Phase 1 trial evaluating IMG936, a novel ADAM9-targeting ADC being co-developed with MacroGenics, in solid tumors including non-small cell lung, colorectal, pancreatic, gastric, and triple negative breast cancers.
- Entered into an exclusive license with Viridian Therapeutics, Inc. to develop and commercialize an insulin-like growth factor-1 receptor (IGF-1R) antibody for all non-oncology indications that do not use radiopharmaceuticals in exchange for an upfront payment, with the potential to receive additional development milestone payments of approximately \$50 million and up to \$95 million in sales milestone payments plus mid-single-digit royalties on the commercial sales of any resulting product.

ANTICIPATED UPCOMING EVENTS

- Present updated data from the IMG632 monotherapy BPDCN expansion cohort in an oral presentation at the American Society of Hematology (ASH) Annual Meeting in December, which will build upon the abstract data recently released showing an overall response rate of 30% in 23 heavily pretreated, relapsed/refractory patients, along with a favorable safety and tolerability profile, without capillary leak syndrome or need for hospitalization for administration. A trial-in-progress poster on the AML monotherapy and combination cohorts will also be presented.
- Support initiation of an investigator sponsored, randomized trial comparing mirvetuximab plus carboplatin versus standard platinum-based therapy in recurrent platinum-sensitive ovarian cancer.

FINANCIAL RESULTS

Revenues for the quarter ended September 30, 2020 were \$18.2 million, compared with \$13.3 million for the quarter ended September 30, 2019, which consisted primarily of non-cash royalty revenues.

Operating expenses for the third quarter of 2020 were \$34.9 million, compared with \$31.2 million for the same quarter in 2019. The increase was largely driven by R&D expenses, which were \$24.7 million in the third quarter of 2020, compared with \$21.0 million for the third quarter of 2019. This increase was primarily due to greater clinical trial expenses driven by costs related to the Company's MIRASOL, SORAYA, and IMG632 studies and lower partner cost-sharing reimbursements. General and administrative expenses for the third quarter of 2020 increased to \$10.2 million compared to \$9.2 million for the third quarter of 2019, primarily due to increased professional fees. Operating expenses for the prior quarter included a \$1.0 million restructuring charge related to retention costs.

Net loss for the third quarter of 2020 was \$22.4 million, or \$0.13 per basic and diluted share, compared to a net loss of \$21.8 million, or \$0.15 per basic and diluted share, for the third quarter of 2019. Weighted average shares outstanding increased to 174.5 million from 148.5 million in the prior year.

ImmunoGen had \$188.2 million in cash and cash equivalents as of September 30, 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 \$87.2 million for the first nine months of 2020, compared with cash used in operations of \$55.8 million for the same period in 2019. The prior year period benefited from \$65.2 million of net proceeds generated from the sale of the Company's residual rights to Kadcyra® (ado-trastuzumab emtansine) royalties in January 2019. Net proceeds from the sale of equipment were \$0.6 million for the first nine months of 2020 compared with capital expenditures of \$(2.8) million for the same period in 2019.



In October 2020, the Company sold 12.9 million shares of its common stock through its At-the-Market (“ATM”) facility, generating net proceeds to the Company of approximately \$54 million, after deducting underwriting discounts and estimated offering expenses. Additionally, pursuant to a collaboration agreement executed with Huadong Medicine in October 2020, the Company received a \$40 million upfront payment.

FINANCIAL GUIDANCE

ImmunoGen has updated its financial guidance for 2020 as follows:

- revenues between \$60 million and \$65 million;
- operating expenses between \$160 million and \$165 million; and
- cash and cash equivalents at December 31, 2020 to be between \$245 million and \$250 million.

Revenue guidance does not include any potential impact from the agreement with Huadong Medicine. ImmunoGen expects that its current cash, inclusive of the \$40 million upfront payment received from the collaboration agreement with Huadong Medicine and \$54 million of net proceeds generated from the recent ATM facility, as well as anticipated future 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 9864218. 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 occurrence, timing, and outcome of potential pre-clinical, clinical, and regulatory events related to ImmunoGen's product candidates; and the presentation of pre-clinical and clinical data on ImmunoGen'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 ImmunoGen's pre-clinical and 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; ImmunoGen's ability to financially support its product programs; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting impact on ImmunoGen's industry and business; and other factors more fully described in ImmunoGen's Annual Report on Form 10-K for the year ended December 31, 2019 and other reports filed with the Securities and Exchange Commission.

INVESTOR RELATIONS AND MEDIA

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

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30 2020	December 31, 2019
ASSETS		
Cash and cash equivalents	\$ 188,217	\$ 176,225
Other assets	59,735	59,037
Total assets	<u>\$ 247,952</u>	<u>\$ 235,262</u>
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current portion of deferred revenue	\$ 3,985	\$ 309
Other current liabilities	95,836	77,101
Long-term portion of deferred revenue	126,541	127,123
Other long-term liabilities	64,481	106,850
Shareholders' deficit	(42,891)	(76,121)
Total liabilities and shareholders' deficit	<u>\$ 247,952</u>	<u>\$ 235,262</u>



CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30		Nine Months Ended September 30	
	2020	2019	2020	2019
Revenues:				
Non-cash royalty revenue	\$ 18,087	\$ 13,202	\$ 45,159	\$ 32,102
License and milestone fees	97	79	1,325	5,237
Research and development support	5	-	17	68
Total revenues	18,189	13,281	46,501	37,407
Expenses:				
Research and development	24,685	21,015	75,014	88,467
General and administrative	10,231	9,208	28,862	28,686
Restructuring charge	-	1,020	1,524	20,921
Total operating expenses	34,916	31,243	105,400	138,074
Loss from operations	(16,727)	(17,962)	(58,899)	(100,667)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(5,645)	(4,275)	(17,428)	(11,525)
Interest expense on convertible bonds	(24)	(24)	(71)	(71)
Other income, net	22	511	638	3,316
Net loss	\$ (22,374)	\$ (21,750)	\$ (75,760)	\$ (108,947)
Basic and diluted net loss per common share	\$ (0.13)	\$ (0.15)	\$ (0.44)	\$ (0.74)
Basic and diluted weighted average common shares outstanding	174,508	148,479	172,215	148,143