

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): July 31, 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 July 31, 2020, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the company's financial results for the quarter and six months ended June 30, 2020. The press release announcing financial results for the quarter and six months ended June 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 July 31, 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: July 31, 2020

/s/ David G. Foster

David G. Foster
Vice President, Finance

ImmunoGen Reports Recent Progress and Second Quarter 2020 Financial Results

Encouraging Data from FORWARD II Study of Mirvetuximab in Combination with Avastin® in Recurrent Ovarian Cancer, Regardless of Platinum Status, Presented at ASCO

Preclinical Data on Next Generation Anti-FR α ADC, IMG151, Demonstrating Enhanced Anti-Tumor Activity, Presented at AACR

Positive Opinion on Orphan Drug Designation for IMG632 for Treatment of BPDCN Adopted by EMA's COMP

IND Application for Novel ADAM9-Targeting ADC, IMG936, Accepted by FDA

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

Waltham, MA – July 31, 2020 – **ImmunoGen, Inc.** (Nasdaq: IMG1), 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 June 30, 2020.

“Despite the challenges of operating in a fully remote environment due to the pandemic, our performance in the second quarter was marked by sound execution and important data presentations and regulatory milestones,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “In an oral presentation at ASCO, we shared data demonstrating the potential of mirvetuximab to serve as the combination agent of choice with Avastin in recurrent ovarian cancer, with an overall response rate in the platinum-resistant subset more than twice the response rate observed with Avastin plus chemotherapy combinations in this population and, in the platinum-sensitive subset, an overall response rate higher than previously seen with platinum-based doublets. We also presented preclinical data at AACR for IMG151 that support development of this next generation ADC in a wide array of FR α -positive tumor types. On the regulatory front, we were pleased that EMA’s Committee for Orphan Medicinal Products adopted a positive opinion to grant IMG632 orphan drug designation for the treatment of BPDCN and that FDA accepted the IND application for IMG936. Further, we strengthened our management team by welcoming Stacy Coen as our Chief Business Officer and Susan Altschuller, PhD as our Chief Financial Officer.”

Enyedy continued, “While we have maintained a high level of productivity over the last quarter, the impact of COVID-19 has slowed site activation and patient enrollment for SORAYA, which we believe will result in a limited delay of six- to eight-weeks in the readout of topline data. With conditions improving in Europe, we expect to accelerate both SORAYA and MIRASOL over the remainder of 2020 and continue to anticipate the BLA for mirvetuximab in the second half of 2021. We also look forward to advancing our monotherapy and combination cohorts for IMG632 and initiating the Phase 1 study of IMG936 in partnership with MacroGenics. Finally, we will provide mature data from our triplet cohort evaluating mirvetuximab in combination with carboplatin and Avastin in patients with recurrent, platinum-sensitive ovarian cancer at ESMO in September and an update on our progress with IMG632 at ASH in December.”

RECENT PROGRESS

- Presented data from the FORWARD II study evaluating mirvetuximab in combination with Avastin (bevacizumab) in recurrent ovarian cancer, regardless of platinum status, in an oral presentation at the virtual American Society of Clinical Oncology (ASCO) Annual Meeting.
 - Continued site activation and patient enrollment in the pivotal SORAYA and confirmatory MIRASOL trials, with sites opening in multiple countries in Europe during the quarter.
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- Received positive opinion from the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) to grant IMG632 orphan drug designation for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN).
- Advanced 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/refractory AML patients.
- Received acceptance for an investigational new drug (IND) application for IMGC936, a novel ADAM9-targeting ADC being co-developed with MacroGenics, from the US Food and Drug Administration (FDA).
- Presented compelling preclinical data evaluating our next generation anti-folate receptor alpha (FR α) ADC, IMG151, in ovarian cancer and other tumor types in a poster at the virtual American Association for Cancer Research (AACR) Annual Meeting.
- Transitioned IMG151 into preclinical development.
- Appointed Stacy Coen as Chief Business Officer and Susan Altschuller, PhD as Chief Financial Officer.

ANTICIPATED UPCOMING EVENTS

- Present mature data from the FORWARD II platinum-sensitive triplet cohort evaluating mirvetuximab in combination with carboplatin and bevacizumab at the European Society for Medical Oncology (ESMO) Congress in September.
- Support initiation of an investigator sponsored, randomized trial comparing mirvetuximab plus carboplatin versus standard platinum-based therapy in recurrent platinum-sensitive ovarian cancer in the fourth quarter.
- Present updated data from the IMG632 monotherapy BPDCN expansion and progress on the AML monotherapy and combination cohorts at the American Society of Hematology (ASH) Annual Meeting in December.
- Initiate Phase 1 trial for IMGC936 in ADAM-9 positive solid tumors including non-small cell lung, pancreatic, gastric, and triple negative breast cancer in the fourth quarter.

FINANCIAL RESULTS

Revenues for the quarter ended June 30, 2020 were \$15.0 million, compared with \$15.5 million for the quarter ended June 30, 2019. Revenues in the second quarter of 2020 included \$14.1 million in non-cash royalty revenues, compared with \$10.4 million for the second quarter of 2019. License and milestone fees of \$5.1 million for the second quarter of 2019 included recognition and receipt of a \$5 million partner milestone, compared to \$0.9 million of upfront license fees recognized in the second quarter of 2020.

Operating expenses for the second quarter of 2020 were \$33.4 million, compared with \$56.6 million for the same quarter in 2019. The decrease was primarily driven by a \$19.3 million restructuring charge recorded in the prior period. Operating expenses for the current period included a \$0.7 million restructuring charge related to retention costs. R&D expenses were \$22.9 million in the second quarter of 2020, compared with \$28.6 million for the second quarter of 2019. This decrease was primarily due to lower expenses resulting from the restructuring of the business at the end of the second quarter of 2019, including decreases in personnel, facility, and third-party research expenses. Partially offsetting these decreases, clinical trial expenses increased in the current quarter driven by costs related to the Company's MIRASOL, SORAYA, and IMG632 combination therapy studies. General and administrative expenses for the second quarter of 2020 increased to \$9.8 million compared to \$8.7 million for the second quarter of 2019, primarily due to increased professional fees and a higher allocation of facility-related expenses for excess laboratory and office space, partially offset by lower personnel expenses.

Net loss for the second quarter of 2020 was \$24.3 million, or \$0.14 per basic and diluted share, compared to a net loss of \$43.4 million, or \$0.29 per basic and diluted share, for the second quarter of 2019. Weighted average shares outstanding increased to 174.4 million from 148.1 million in the prior year.

ImmunoGen had \$219.5 million in cash and cash equivalents as of June 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 \$56.5 million for the first six months of 2020, compared with cash used in operations of \$20.8 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 \$1.4 million for the first six months of 2020 compared with capital expenditures of \$(2.4) million for the same period in 2019.

FINANCIAL GUIDANCE

ImmunoGen's financial guidance for 2020 remains unchanged:

- 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 is preparing for potential accelerated approval for mirvetuximab in platinum-resistant ovarian cancer and is planning for increased investment in 2021 related to manufacturing in support of commercial launch. With the addition of these investments, the Company expects that its current cash and anticipated cash receipts from partners will fund operations into the second quarter 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 4388395. 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: ImmunoGen's revenues and operating expenses for the twelve months ending December 31, 2020; ImmunoGen's cash and marketable securities as of December 31, 2020; the length of time that ImmunoGen's cash and anticipated cash receipts from partners will fund operations; 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 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 ImmunoGen'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; 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 CONTACTS

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

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2020	December 31, 2019
ASSETS		
Cash and cash equivalents	\$ 219,506	\$ 176,225
Other assets	50,222	59,037
Total assets	<u>\$ 269,728</u>	<u>\$ 235,262</u>
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current portion of deferred revenue	\$ 80	\$ 309
Other current liabilities	90,799	77,101
Long-term portion of deferred revenue	126,535	127,123
Other long-term liabilities	76,837	106,850
Shareholders' deficit	(24,523)	(76,121)
Total liabilities and shareholders' deficit	<u>\$ 269,728</u>	<u>\$ 235,262</u>



CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Month Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Non-cash royalty revenue	\$ 14,075	\$ 10,412	\$ 27,072	\$ 18,900
License and milestone fees	945	5,079	1,228	5,158
Research and development support	5	51	12	68
Total revenues	15,025	15,542	28,312	24,126
Expenses:				
Research and development	22,921	28,559	50,329	67,452
General and administrative	9,767	8,700	18,631	19,478
Restructuring charge	699	19,342	1,524	19,901
Total operating expenses	33,387	56,601	70,484	106,831
Loss from operations	(18,362)	(41,059)	(42,172)	(82,705)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(6,081)	(3,818)	(11,783)	(7,250)
Interest expense on convertible bonds	(23)	(23)	(47)	(47)
Other income, net	168	1,454	616	2,805
Net loss	\$ (24,298)	\$ (43,446)	\$ (53,386)	\$ (87,197)
Basic and diluted net loss per common share	\$ (0.14)	\$ (0.29)	\$ (0.31)	\$ (0.59)
Basic and diluted weighted average common shares outstanding	174,354	148,129	171,055	147,972