

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 30, 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 July 30, 2021, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the company's financial results for the quarter and six months ended June 30, 2021. The press release announcing financial results for the quarter and six months ended June 30, 2021 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 30, 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: July 30, 2021

/s/ Renee Lentini
Renee Lentini
Vice President, Chief Accounting Officer

ImmunoGen Reports Recent Progress and Second Quarter 2021 Financial Results

Compelling Final Data from FORWARD II Study Combining Mirvetuximab Soravtansine with Avastin® in Recurrent Ovarian Cancer, Regardless of Platinum Status, Presented at ASCO

Top-line Data from Pivotal SORAYA Trial on Track for Q4 Release

Continued Progress in Ongoing MIRASOL, IMG632, and IMG936 Studies

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

Waltham, MA – July 30, 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 ended June 30, 2021.

"With top-line data from our pivotal SORAYA trial on track for release in Q4, we have accelerated preparations for the BLA submission and commercial launch of mirvetuximab. In parallel, we continue to generate data that support mirvetuximab as the combination agent of choice for ovarian cancer patients," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "At ASCO, we presented final data from our mirvetuximab plus Avastin® doublet, showing compelling and durable anti-tumor activity, with a 64% ORR, 11.8 month mDOR, and 10.6 month mPFS in patients with high FR α recurrent ovarian cancer, regardless of platinum status. We believe these data are highly encouraging, particularly given outcomes with available therapies in this setting. As we continue to accrue our confirmatory MIRASOL trial, we are working to establish mirvetuximab as the new standard of care in patients with high FR α ovarian cancer, who comprise roughly 40% of the market. To this end, this quarter we are initiating PICCOLO, a single-arm study of mirvetuximab monotherapy in recurrent platinum-sensitive ovarian cancer to support label expansion."

Enyedy added, "Beyond mirvetuximab, our IMG632, IMG936, and IMG151 programs are progressing as anticipated. Patient accrual continues in our IMG632 trials in BPDCN and AML, with data from our AML cohort expected at ASH next quarter. Our dose-escalation study of IMG936 is enrolling in multiple solid tumor types and we are on track to file the IND for IMG151 by year-end. With a focus on execution towards key inflection points, we look forward to transforming ImmunoGen into a fully integrated oncology company with the potential for two innovative ADCs on the market in 2022."

RECENT PROGRESS

- Presented final data from the FORWARD II study evaluating mirvetuximab in combination with Avastin® (bevacizumab) in patients with medium and high folate receptor alpha (FR α)-expressing recurrent ovarian cancer for whom a non-platinum based combination regimen is appropriate at the 2021 American Society of Clinical Oncology (ASCO) Virtual Annual Meeting.
 - Completed accrual in the pivotal SORAYA study and further enrolled patients in the confirmatory MIRASOL study for mirvetuximab.
 - Supported enrollment of investigator-sponsored trials of mirvetuximab plus carboplatin in a single-arm study in the neoadjuvant setting and in a randomized study in patients with recurrent platinum-sensitive ovarian cancer.
 - Advanced accrual in the pivotal 801 Phase 2 study of IMG632 in frontline and relapsed/refractory (R/R) blastic plasmacytoid dendritic cell neoplasm (BPDCN).
 - Continued patient enrollment in the 802 Phase 1b/2 study of IMG632 in combination with Vidaza® (azacitidine) and Venclexta® (venetoclax) in R/R acute myeloid leukemia (AML) patients and as a monotherapy in minimal residual disease positive (MRD+) AML.
 - Escalated dosing in the Phase 1 study of IMG936 in multiple solid tumor types.
 - Progressed activities to support an investigational new drug (IND) application for IMG151.
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ANTICIPATED UPCOMING EVENTS

- Release top-line data from the pivotal SORAYA study in the fourth quarter of 2021 and submit the biologics license application (BLA) in the first quarter of 2022 to support potential accelerated approval in 2022.
- Generate top-line data for the confirmatory MIRASOL study in the third quarter of 2022.
- Enroll the first patient in PICCOLO, a single-arm study of mirvetuximab monotherapy in high FR α recurrent platinum-sensitive ovarian cancer, in the third quarter of 2021, designed to support potential label expansion.
- Present initial AML combination data for IMG632 at the 2021 American Society of Hematology (ASH) Annual Meeting in December 2021.
- Complete dose-escalation in the Phase 1 study evaluating IMG936, with initial data anticipated in early 2022.
- Submit the IND application for IMG151 by the end of 2021.

FINANCIAL RESULTS

Revenues for the quarter ended June 30, 2021 were \$16.9 million, compared with \$15.0 million for the quarter ended June 30, 2020, which consisted primarily of non-cash royalty revenues.

Operating expenses for the second quarter of 2021 were \$44.3 million, compared with \$33.4 million for the same quarter in 2020. The increase was largely driven by research and development expenses, which were \$34.6 million for the second quarter of 2021, compared with \$22.9 million for the second quarter of 2020. This increase was due to greater clinical trial expenses driven by costs related to the MIRASOL, SORAYA, and IMG936 studies, greater personnel and temporary staffing costs, and higher external manufacturing costs and third-party service fees in support of commercial readiness. General and administrative expenses for the second quarter of 2021 were \$9.7 million, compared to \$9.8 million for the second quarter of 2020.

Net loss for the second quarter of 2021 was \$30.7 million, or \$0.15 per basic and diluted share, compared to a net loss of \$24.3 million, or \$0.14 per basic and diluted share, for the second quarter of 2020. Weighted average shares outstanding increased to 199.9 million for the 2021 period from 174.4 million in the prior year.

ImmunoGen had \$239.5 million in cash and cash equivalents as of June 30, 2021, compared with \$293.9 million as of December 31, 2020, and had \$1.1 million of convertible debt outstanding as of June 30, 2021, compared with \$2.1 million as of December 31, 2020. Cash used in operations was \$88.5 million for the first six months of 2021, compared with cash used in operations of \$56.5 million for the same period in 2020. Capital expenditures were \$(0.9) million for the first six months of 2021, compared with net proceeds from the sale of equipment of \$1.4 million for the first six months of 2020.

FINANCIAL GUIDANCE

ImmunoGen's financial guidance for 2021 remains unchanged:

- 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 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 1789134. The call may also be accessed through the Investors and Media section of the Company's website, www.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®, 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; how long its current cash will fund operations, 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 as set forth in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2021, and other reports filed with the Securities and Exchange Commission.

INVESTOR RELATIONS AND MEDIA CONTACTS

ImmunoGen

Courtney O'Konek

781-895-0600

courtney.okonek@immunogen.com

OR

FTI Consulting

Robert Stanislaro

212-850-5657

robert.stanislaro@fticonsulting.com

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

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2021	December 31, 2020
ASSETS		
Cash and cash equivalents	\$ 239,538	\$ 293,856
Other assets	61,908	61,216
Total assets	<u>\$ 301,446</u>	<u>\$ 355,072</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current portion of deferred revenue	\$ 53,792	\$ 29,249
Other current liabilities	66,527	93,074
Long-term portion of deferred revenue	55,480	80,860
Other long-term liabilities	57,182	62,319
Shareholders' equity	68,465	89,570
Total liabilities and shareholders' equity	<u>\$ 301,446</u>	<u>\$ 355,072</u>



CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Non-cash royalty revenue	\$ 16,690	\$ 14,075	\$ 32,235	\$ 27,072
License and milestone fees	252	945	409	1,228
Research and development support	6	5	10	12
Total revenues	16,948	15,025	32,654	28,312
Expenses:				
Research and development	34,589	22,921	69,002	50,329
General and administrative	9,728	9,767	19,937	18,631
Restructuring charge	-	699	-	1,524
Total operating expenses	44,317	33,387	88,939	70,484
Loss from operations	(27,369)	(18,362)	(56,285)	(42,172)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(3,557)	(6,081)	(8,201)	(11,783)
Interest expense on convertible bonds	(23)	(23)	(47)	(47)
Other income (loss), net	208	168	(259)	616
Net loss	\$ (30,741)	\$ (24,298)	\$ (64,792)	\$ (53,386)
Basic and diluted net loss per common share	\$ (0.15)	\$ (0.14)	\$ (0.32)	\$ (0.31)
Basic and diluted weighted average common shares outstanding	199,890	174,354	199,365	171,055