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): May 10, 2021

ImmunoGen, Inc.

(Exact name of registrant as specified in its charter)

Massachusetts	**0-17999**	**04-2726691**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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:

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
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 May 10, 2021, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the company's financial results for the quarter ended March 31, 2021. The press release announcing financial results for the quarter ended March 31, 2021 is included as Exhibit 99.1 and incorporated herein by reference.

ITEM 9.01 Financial Statements and Exhibits.

(d): Exhibits

Exhibit No.	Exhibit
99.1	Press Release of ImmunoGen, Inc. dated May 10, 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: May 10, 2021

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

Exhibit 99.1

ImmunoGen Reports Recent Progress and First Quarter 2021 Financial Results

Top-Line Data from Pivotal SORAYA Trial of Mirvetuximab Soravtansine in Ovarian Cancer Expected in the Fourth Quarter of 2021

FORWARD II Mirvetuximab Plus Avastin® Doublet Cohort in Recurrent Ovarian Cancer, Regardless of Platinum Status, Selected for Oral Presentation at ASCO

Preclinical Data Demonstrating Anti-Tumor Activity of First-in-Class ADAM9-Targeting ADC, IMGC936, Presented at AACR

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

Waltham, MA – May 10, 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 March 31, 2021.

"During the first quarter, we advanced our portfolio of innovative ADCs and accelerated preparations for two potential product launches next year," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "We saw a limited delay in patient enrollment in the pivotal SORAYA trial for our lead program, mirvetuximab soravtansine, which has shifted the anticipated timing of top-line data from the third into the fourth quarter of this year and the projected submission of the BLA into the first quarter of 2022. We have also experienced some COVID-related impact on accrual to our confirmatory MIRASOL trial and now expect the read-out on the primary endpoint to move from the second into the third quarter of 2022. Beyond SORAYA and MIRASOL, we are commencing several studies to move mirvetuximab into earlier lines of ovarian cancer therapy, including an investigator-sponsored trial of mirvetuximab in combination with carboplatin in the neoadjuvant setting that initiated this quarter. We are also supporting a randomized study comparing mirvetuximab combined with carboplatin to standard of care in patients with recurrent platinum-sensitive disease and have submitted a protocol to FDA for a single-arm study of mirvetuximab monotherapy in later-line platinum-sensitive patients, with both studies anticipated to begin enrollment in the second half of this year. Finally, we were pleased to receive notice that mature data from our mirvetuximab plus Avastin® doublet cohort in recurrent ovarian cancer, regardless of platinum status, have been selected for an oral presentation at ASCO in June."

Enyedy added, "We continued enrollment for our second pivotal program, IMGN632, in patients with frontline and relapsed/refractory BPDCN, with top-line data expected in the first half of 2022. IMGN632 is also in ongoing development in AML, both as a monotherapy and in combinations. Moving to our earlier-stage portfolio, we presented preclinical data at AACR last month on IMGC936, our first-in-class ADAM9-targeting ADC, demonstrating anti-tumor activity in multiple solid tumor models, and we advanced dose escalation in the Phase 1 study for this program. IND-enabling activities for our next-generation anti-FRα ADC, IMGN151, are on track to submit an application to the FDA by the end of 2021. With pre-commercial activities underway, we look forward to a meaningful year ahead with a number of important milestones across the business as we work towards bringing our first two therapies to market next year."

RECENT PROGRESS

- Further enrolled patients in the pivotal SORAYA and confirmatory MIRASOL trials.
- Supported initiation of an investigator-sponsored trial of mirvetuximab plus carboplatin in the neoadjuvant setting.
- Submitted to the US Food and Drug Administration (FDA) a single-arm study protocol for mirvetuximab monotherapy in later-line platinum-sensitive ovarian cancer patients.
- Advanced accrual of the pivotal 801 Phase 1/2 study of IMGN632 in frontline and relapsed/refractory (R/R) blastic plasmacytoid dendritic cell neoplasm (BPDCN) patients.

- Continued patient enrollment in the 802 Phase 1b/2 study of IMGN632 in combination with Vidaza® (azacitidine) and Venclexta® (venetoclax) in R/R and frontline acute myeloid leukemia (AML) patients and as a monotherapy in minimal residual disease positive (MRD+) AML.
- Presented preclinical data on IMGC936, our novel ADAM9-targeting ADC in co-development with MacroGenics, in a poster at the virtual American Association for Cancer Research (AACR) Annual Meeting.
- Moved through dose-escalation cohorts in the Phase 1 study of IMGC936 in multiple solid tumor types.
- Progressed activities to support an investigational new drug (IND) application for IMGN151.

ANTICIPATED UPCOMING EVENTS

- Generate top-line pivotal SORAYA data 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.
- Complete patient enrollment in MIRASOL and generate top-line data in the third quarter of 2022.
- Present mature data from the Phase 1b FORWARD II cohort evaluating mirvetuximab in combination with Avastin® (bevacizumab) in recurrent ovarian cancer in an oral presentation at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting in June.
- Initiate a single-arm study of mirvetuximab monotherapy in recurrent platinum-sensitive ovarian cancer in the second half of 2021 to support potential label expansion.
- Support the start of a randomized Phase 2 investigator-sponsored study of mirvetuximab plus carboplatin in recurrent platinum-sensitive ovarian cancer in the second half of 2021.
- Present initial AML combination data for IMGN632 at the 2021 American Society of Hematology (ASH) Annual Meeting in December.
- Complete dose escalation in the Phase 1 study evaluating IMGC936, with initial data anticipated in early 2022.
- Submit the IND application for IMGN151 by the end of 2021.

FINANCIAL RESULTS

Revenues for the quarter ended March 31, 2021 were $15.7 million, compared with $13.3 million for the quarter ended March 31, 2020, which consisted primarily of non-cash royalty revenues.

Operating expenses for the first quarter of 2021 were $44.6 million, compared with $37.1 million for the same quarter in 2020. The increase was largely driven by research and development expenses, which were $34.4 million in the first quarter of 2021, compared with $27.4 million for the first quarter of 2020. This increase was primarily due to greater clinical trial expenses driven by costs related to the MIRASOL, SORAYA, and IMGC936 studies, greater external manufacturing costs, and greater personnel and temporary staffing costs. General and administrative expenses for the first quarter of 2021 increased to $10.2 million, compared to $8.9 million for the first quarter of 2020, primarily due to increased professional fees and personnel costs, including greater stock-based compensation. Operating expenses for the first quarter of 2020 included a $0.8 million restructuring charge related to retention costs.

Net loss for the first quarter of 2021 was $34.1 million, or $0.17 per basic and diluted share, compared to a net loss of $29.1 million, or $0.17 per basic and diluted share, for the first quarter of 2020. Weighted average shares outstanding increased to 198.8 million for the 2021 period from 166.9 million in the prior year.

ImmunoGen had $283.1 million in cash and cash equivalents as of March 31, 2021, compared with $293.9 million as of December 31, 2020, and had $2.1 million of convertible debt outstanding in each period. Cash used in operations was $44.6 million for the first three months of 2021, compared with cash used in operations of $28.3 million for the same period in 2020. Capital expenditures were $(0.9) million for the first quarter of 2021, compared with net proceeds from the sale of equipment of $1.4 million for the first quarter 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 9982696. 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®, 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 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

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

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2021	December 31, 2020
ASSETS		
Cash and cash equivalents	$ 283,120	$ 293,856
Other assets	62,842	61,216
Total assets	$ 345,962	$ 355,072
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current portion of deferred revenue	$ 51,515	$ 29,249
Other current liabilities	82,838	93,074
Long-term portion of deferred revenue	58,522	80,860
Other long-term liabilities	58,967	62,319
Shareholders' equity	94,120	89,570
Total liabilities and shareholders' equity	$ 345,962	$ 355,072

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Revenues:		
Non-cash royalty revenue	$ 15,545	$ 12,997
License and milestone fees	157	283
Research and development support	4	7
Total revenues	15,706	13,287
Expenses:		
Research and development	34,413	27,408
General and administrative	10,209	8,864
Restructuring charge	-	825
Total operating expenses	44,622	37,097
Loss from operations	(28,916)	(23,810)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(4,644)	(5,702)
Interest expense on convertible bonds	(24)	(24)
Other (loss) income, net	(467)	448
Net loss	$ (34,051)	$ (29,088)
Basic and diluted net loss per common share	**$ (0.17)**	**$ (0.17)**
Basic and diluted weighted average common shares outstanding	198,835	166,947