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): October 29, 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 October 29, 2021, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the company's financial results for the quarter and nine months ended September 30, 2021. The press release announcing financial results for the quarter and nine months ended September 30, 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 October 29, 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: October 29, 2021

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

Exhibit 99.1

ImmunoGen Reports Recent Progress and Third Quarter 2021 Financial Results

Top-Line Data from Pivotal SORAYA Trial Evaluating Mirvetuximab Soravtansine in Platinum-Resistant Ovarian Cancer on Track for Release this Quarter

IMGN632 AML Combination Data to be Highlighted at ASH Annual Meeting

PICCOLO, Single-Arm Study of Mirvetuximab in Platinum-Sensitive Ovarian Cancer, Open for Enrollment

Earlier-Stage Pipeline Continues to Progress

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

Waltham, MA – October 29, 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 September 30, 2021.

"We look forward to announcing top-line data from our pivotal SORAYA trial this quarter, including data on the primary endpoint of overall response rate and key secondary endpoint of duration of response. With positive data, we will move quickly to complete the BLA, with the goal of submitting the filing in the first quarter of 2022," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "In addition to SORAYA, we continue to advance a broad program to establish mirvetuximab as the standard of care for patients with FRα-positive ovarian cancer. Our confirmatory MIRASOL trial is enrolling at over 160 sites in 18 countries in North America, Europe, Asia, and Australia, and we have initiated the PICCOLO trial, which could support label expansion in recurrent platinum-sensitive ovarian cancer. Beyond mirvetuximab monotherapy, the first patients have been enrolled in the large investigator-sponsored studies evaluating mirvetuximab combined with carboplatin in both the neoadjuvant and recurrent platinum-sensitive settings to support our objective of making mirvetuximab the combination agent of choice in ovarian cancer, and we look forward to sharing our label-enabling combination strategy early next year."

Enyedy continued, "In addition, our IMGN632, IMGC936, and IMGN151 programs are advancing as planned. We anticipate presenting data on IMGN632 in AML at ASH in December, have escalated dosing in multiple solid tumors with our ADAM-9 targeting ADC, IMGC936, and expect to file the IND for IMGN151, our next-generation FRα-targeting ADC, by year-end. As we close out 2021, we remain focused on execution and look forward to transforming ImmunoGen into a fully integrated oncology company with the potential for commercial launch next year."

RECENT PROGRESS

- Further enrolled patients in the confirmatory MIRASOL study for mirvetuximab.
- Initiated PICCOLO, a single-arm study of mirvetuximab monotherapy in high folate receptor alpha (FRα) recurrent platinum-sensitive ovarian cancer.
- Enrolled the first patients in the investigator-sponsored trials of mirvetuximab plus carboplatin in a single-arm study in the neoadjuvant setting and a randomized study in patients with recurrent platinum-sensitive ovarian cancer.
- Advanced accrual in the pivotal 801 Phase 2 study, now known as CADENZA, of IMGN632 in frontline and relapsed/refractory (R/R) blastic plasmacytoid dendritic cell neoplasm (BPDCN).
- Continued patient enrollment in the 802 Phase 1b/2 study of IMGN632 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 IMGC936 in multiple solid tumor types.
- Progressed activities to support an investigational new drug (IND) application for IMGN151.
- Appointed Helen M. Thackray, MD, to the Board of Directors.

ANTICIPATED UPCOMING EVENTS

- Release top-line data from the pivotal SORAYA study this quarter, with the goal of submitting the biologics license application (BLA) in the first quarter of 2022 to support potential accelerated approval in 2022.
- Present initial AML combination data for IMGN632 at the 2021 American Society of Hematology (ASH) Annual Meeting in December.
- Submit the IND application for IMGN151 by the end of 2021.
- Complete dose-escalation in the Phase 1 study evaluating IMGC936, with initial data anticipated in 2022.
- Generate top-line data for the confirmatory MIRASOL study in the third quarter of 2022.

FINANCIAL RESULTS

Revenues for the quarter ended September 30, 2021 were $9.2 million, compared with $18.2 million for the quarter ended September 30, 2020. This decrease was driven by a reduction in non-cash royalty revenue due to the completion of the first tranche of payments under the 2015 transaction covering the sale of Kadcyla® royalties. Revenues for the quarter ended September 30, 2021 also included recognition of an anticipated $2.5 million partner development milestone fee.

Operating expenses for the third quarter of 2021 were $43.4 million, compared with $34.9 million for the same quarter in 2020. Research and development expenses rose to $33.1 million for the third quarter of 2021, compared with $24.7 million for the third quarter of 2020, driven by increases in clinical trial expenses, personnel and temporary staffing costs, and third-party service fees in support of commercial readiness. General and administrative expenses were essentially flat at $10.3 million and $10.2 million for the third quarters of 2021 and 2020, respectively.

Net loss for the third quarter of 2021 was $37.3 million, or $0.18 per basic and diluted share, compared to a net loss of $22.4 million, or $0.13 per basic and diluted share, for the third quarter of 2020. Weighted average shares outstanding increased to 204.8 million for the 2021 period from 174.5 million in the prior year.

ImmunoGen had $245.8 million in cash and cash equivalents as of September 30, 2021, compared with $293.9 million as of December 31, 2020, and had $2.1 million of convertible debt outstanding as of December 31, 2020. There was no convertible debt outstanding as of September 30, 2021. Cash used in operations was $123.5 million for the first nine months of 2021, compared with cash used in operations of $87.2 million for the same period in 2020. Capital expenditures were $(1.1) million for the first nine months of 2021, compared with net proceeds from the sale of equipment of $0.6 million for the first nine months of 2020.

During the quarter ended September 30, 2021, the Company sold 2.2 million shares of its common stock through its At-the-Market (ATM) facility, generating gross proceeds to the Company of approximately $13 million. In August 2021, the Company entered into a Securities Purchase Agreement pursuant to which the Company agreed to sell to an investor a warrant to purchase up to an aggregate of 5,434,782 shares of the Company's common stock for a nominal value, generating additional gross proceeds of approximately $30 million.

FINANCIAL GUIDANCE

ImmunoGen has updated its financial guidance for 2021 and now expects:

- revenues between $65 million and $75 million;
- operating expenses between $190 million and $200 million; and
- cash and cash equivalents at December 31, 2021 to be between $190 million and $200 million.

ImmunoGen expects that its current cash will fund operations into the fourth 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 1587202. 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.

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 2021 and its cash and cash equivalents as of December 31, 2021; how long its current cash is expected to fund operations; the occurrence, timing, and outcome of potential preclinical, clinical, and regulatory events related to, and the potential benefits of, the Company's product candidates including the submission of the Company's IND to the FDA for IMGN151, the submission of the Company's BLA to the FDA for mirvetuximab, and the launch of two ADCs next year; and the timing and presentation of preclinical and clinical data on the Company's product candidates, including the release of top-line data from the pivotal SORAYA study in the fourth quarter of 2021 and the confirmatory MIRASOL study in the third quarter of 2022. 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 timing and outcome of the Company's anticipated interactions with regulatory authorities; obtaining, maintaining, and protecting the Company's intellectual property; 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)

	September 30, 2021	December 31, 2020
ASSETS		
Cash and cash equivalents	$ 245,761	$ 293,856
Other assets	51,042	61,216
Total assets	$ 296,803	$ 355,072
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current portion of deferred revenue	$ 53,526	$ 29,249
Other current liabilities	58,259	93,074
Long-term portion of deferred revenue	52,479	80,860
Other long-term liabilities	55,446	62,319
Shareholders' equity	77,093	89,570
Total liabilities and shareholders' equity	$ 296,803	$ 355,072

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Non-cash royalty revenue	$ 6,533	$ 18,087	$ 38,768	$ 45,159
License and milestone fees	2,677	97	3,086	1,325
Research and development support	-	5	10	17
Total revenues	9,210	18,189	41,864	46,501
Expenses:				
Research and development	33,147	24,685	102,149	75,014
General and administrative	10,297	10,231	30,234	28,862
Restructuring charge	-	-	-	1,524
Total operating expenses	43,444	34,916	132,383	105,400
Loss from operations	(34,234)	(16,727)	(90,519)	(58,899)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(2,751)	(5,645)	(10,952)	(17,428)
Interest expense on convertible bonds	-	(24)	(47)	(71)
Other (loss) income, net	(354)	22	(613)	638
Net loss	$ (37,339)	$ (22,374)	$ (102,131)	$ (75,760)
Basic and diluted net loss per common share	**$ (0.18)**	**$ (0.13)**	**$ (0.51)**	**$ (0.44)**
Basic and diluted weighted average common shares outstanding	204,844	174,508	201,212	172,215