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 6, 2022

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 6, 2022, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the Company's financial results for the quarter ended March 31, 2022. The press release announcing financial results for the quarter ended March 31, 2022 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 6, 2022
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 6, 2022

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

Exhibit 99.1

ImmunoGen Reports Recent Progress and First Quarter 2022 Financial Results

Submitted BLA for Mirvetuximab Soravtansine Monotherapy to FDA Under Accelerated Approval Pathway; Commercial Preparations Underway

Presented Results from Positive Pivotal SORAYA Trial of Mirvetuximab Soravtansine in Ovarian Cancer in Plenary Session at SGO Annual Meeting; Additional Efficacy and Safety Data to be Highlighted at ASCO

Top-Line Data from Confirmatory MIRASOL Trial Now Expected in Early 2023 Based on Recent Reforecast of Projected PFS Events

Progressing Second Pivotal Program, Pivekimab Sunirine, with Top-Line Data in BPDCN Anticipated Before Year-End; Enrollment Ongoing in Phase 1b/2 Expansion Triplet Cohorts in AML

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

Waltham, MA – May 6, 2022 – 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, 2022.

"Following the presentation of the results from our positive pivotal SORAYA trial at SGO, we were pleased to submit the BLA to support the accelerated approval of mirvetuximab monotherapy in FRα-high platinum-resistant ovarian cancer. We requested Priority Review for the BLA and look forward to acceptance towards the end of May and a PDUFA date on the application later this year," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "In preparation for potential commercialization, we have significantly ramped our launch readiness activities, with a focus on increasing mirvetuximab and FRα awareness among prescribers."

Enyedy continued, "The broader mirvetuximab program is also advancing nicely, with accrual accelerating in MIRASOL following the release of the SORAYA results in late November, enrollment continuing in PICCOLO, and initiation of our GLORIOSA and Trial 0420 combination studies anticipated by mid-year. Based upon a reforecast generated in conjunction with the recent pre-specified interim futility analysis for MIRASOL, we now expect to reach the requisite number of PFS events in the fourth quarter and will report top-line data from MIRASOL in early 2023. Turning to our second pivotal program, pivekimab, with the recommended phase 2 dose for the triplet in combination with azacitidine and venetoclax determined, we have moved forward with expansion cohorts in both frontline and relapsed AML patients and are on track to report preliminary efficacy data from our pivotal CADENZA study in BPDCN before year-end. Regarding our earlier-stage programs, dose-escalation continues in the Phase 1 trial of IMGC936 in multiple solid tumors and the activities to generate the CMC information needed for our IND for IMGN151 are on track. With a strong start and intense focus on execution, we are well positioned to deliver on our near-term objectives and transform ImmunoGen into a fully-integrated oncology company this year."

RECENT PROGRESS

- Submitted the biologics license application (BLA) under the accelerated approval pathway to the US Food and Drug Administration (FDA) for mirvetuximab soravtansine (mirvetuximab) monotherapy in patients with folate receptor alpha (FRα)-high platinum-resistant ovarian cancer who have been previously treated with 1 to 3 prior systemic treatments.

- Presented results from the pivotal SORAYA trial of mirvetuximab, demonstrating impressive anti-tumor activity and durability of response, together with a differentiated safety profile, at the Society of Gynecologic Oncology (SGO) 2022 Annual Meeting.
- Continued enrollment in the confirmatory MIRASOL study and recently completed a pre-specified interim futility analysis with a recommendation from the Independent Data Monitoring Committee for MIRASOL to proceed without modification.
- Advanced accrual in PICCOLO, a single-arm study of mirvetuximab monotherapy in FRα-high recurrent platinum-sensitive ovarian cancer.
- Supported 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.
- Progressed the pivotal Phase 2 CADENZA study of pivekimab sunirine (pivekimab, formerly IMGN632) in frontline and relapsed/refractory (R/R) blastic plasmacytoid dendritic cell neoplasm (BPDCN).
- Initiated expansion cohorts in the Phase 1b/2 study evaluating pivekimab, Vidaza® (azacitidine), and Venclexta® (venetoclax) in both relapsed and frontline unfit acute myeloid leukemia (AML) patients.
- Advanced dose escalation and opened additional sites in the Phase 1 study of IMGC936 in multiple solid tumor types.
- Progressed the generation of supplemental chemistry, manufacturing, and controls (CMC) information to the FDA to support the investigational new drug (IND) application for IMGN151.
- Announced a global licensing agreement granting Eli Lilly and Company (Lilly) exclusive rights to research, develop, and commercialize ADCs directed to targets selected by Lilly based on ImmunoGen's novel camptothecin technology in exchange for up to $1.7 billion in potential exercise fees and milestone payments.

ANTICIPATED UPCOMING EVENTS

- Potential for BLA acceptance by FDA under the accelerated approval pathway for mirvetuximab as a monotherapy in patients with FRα-high platinum-resistant ovarian cancer who have been previously treated with 1 to 3 prior systemic treatments.
- Present additional efficacy and safety analyses from the mirvetuximab program at the American Society of Clinical Oncology (ASCO) Annual Meeting in June.
- Generate top-line data for MIRASOL in early 2023.
- Initiate two combination studies for mirvetuximab in platinum-sensitive ovarian cancer by mid-2022: Trial 0420, a single-arm Phase 2 trial of mirvetuximab in combination with carboplatin followed by mirvetuximab continuation in FRα-low, medium, and high patients; and GLORIOSA, a randomized Phase 3 trial of mirvetuximab in combination with Avastin® (bevacizumab) maintenance in FRα-high patients.
- Report preliminary efficacy data from the pivotal CADENZA study of pivekimab in BPDCN before year-end.
- Present initial data from frontline and relapsed AML expansion cohorts combining pivekimab, azacitidine, and venetoclax at the 2022 American Society of Hematology (ASH) Annual Meeting in December.
- Complete dose-escalation in the Phase 1 study evaluating IMGC936, with initial data anticipated before year-end.
- Begin enrollment in the Phase 1 study of IMGN151 following the submission of supplemental CMC information to the FDA.

FINANCIAL RESULTS

Total revenues were $38.1 million for the quarter ended March 31, 2022 compared to $15.7 million for the quarter ended March 31, 2021. The increase was driven by the recognition of $21.6 million of fees previously received and deferred pursuant to the Company's collaboration agreement with Huadong Medicine and the recognition of $9.2 million of a $13.0 million upfront payment received pursuant to the Company's license agreement with Lilly in the first quarter of 2022. Partially offsetting these increases, non-cash royalty revenue decreased $9.1 million due to the completion of the first tranche of payments under the 2015 KADCYLA® royalty agreement in the second quarter of 2021.

Operating expenses for the quarter ended March 31, 2022 were $60.9 million, compared with $44.6 million for the same quarter in 2021. Research and development expenses rose to $44.3 million for the quarter ended March 31, 2022 compared to $34.4 million for the quarter ended March 31, 2021, driven by increases in

personnel and temporary staffing costs, regulatory filing fees, third-party service fees, and external manufacturing costs in support of commercial readiness. Selling, general and administrative expenses increased to $16.6 million for the quarter ended March 31, 2022 compared to $10.2 million for the quarter ended March 31, 2021, due primarily to building commercial capabilities, including the hiring of personnel, in anticipation of a potential US launch of mirvetuximab in the second half of 2022.

Net loss for the first quarter of 2022 was $24.1 million, or $0.10 per basic and diluted share, compared to a net loss of $34.1 million, or $0.17 per basic and diluted share, for the first quarter of 2021. Weighted average shares outstanding increased to 253.3 million for the 2022 period from 198.8 million in the prior year.

ImmunoGen had $437.7 million in cash and cash equivalents as of March 31, 2022, compared with $478.8 million as of December 31, 2021. Cash used in operations was $41.4 million for the first three months of 2022, compared with cash used in operations of $44.6 million for the same period in 2021, with the current period benefitting from a $13.0 million upfront license payment received from Lilly. Capital expenditures were $0.3 million and $0.9 million for the first three months of 2022 and 2021, respectively.

FINANCIAL GUIDANCE
ImmunoGen's financial guidance for 2022 remains unchanged; the Company continues to expect:

- revenues between $75 million and $85 million;
- operating expenses between $285 million and $295 million; and
- cash and cash equivalents at December 31, 2022 to be between $245 million and $255 million.

Given the range in timing for potential approval, revenue guidance does not yet include potential product sales from mirvetuximab.

ImmunoGen expects that its current cash, combined with anticipated product and collaboration revenues, will fund operations into 2024.

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 5444669. 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. These statements include, but are not limited to, ImmunoGen's expectations related to: the Company's revenues and operating expenses for 2022 and its cash and cash equivalents as of December 31, 2022; the Company's anticipated cash runway; 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, but not limited to: the accelerated approval of the Company's BLA to the FDA for mirvetuximab, the commercial launch of mirvetuximab, the initiation of Trial 0420, the GLORIOSA Phase 3 trial, the expansion cohort combining pivekimab, azacitidine, and venetoclax in frontline AML, the completion of the dose-escalation Phase 1 study evaluating IMGC936 and the dosing of patients in a Phase 1 study for IMGN151; the timing and presentation of preclinical and clinical data on the Company's product candidates, including additional safety and efficacy data from SORAYA, top-line data for the MIRASOL study, top-line data from the CADENZA study, initial data from the frontline and relapsed AML expansion cohorts; and initial data from the Phase 1 dose-escalation study evaluating IMGC936; and the Company's business and product development strategies. 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, including that the FDA may

determine that our BLA for mirvetuximab is not complete and acceptable for filing or does not meet the conditions for accelerated approval; 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 February 28, 2022, and other reports filed with the Securities and Exchange Commission. The forward-looking statements in this press release speak only as of the date of this press release. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable law.

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)

	March 31, 2022	December 31, 2021
ASSETS		
Cash and cash equivalents	$ 437,661	$ 478,750
Other assets	44,048	47,015
Total assets	$ 481,709	$ 525,765
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current portion of deferred revenue	$ 23,417	$ 44,351
Other current liabilities	60,701	56,594
Long-term portion of deferred revenue	46,694	47,717
Other long-term liabilities	44,429	51,517
Shareholders' equity	306,468	325,586
Total liabilities and shareholders' equity	$ 481,709	$ 525,765

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Revenues:		
License and milestone fees	$ 30,892	$ 157
Non-cash royalty revenue	6,428	15,545
Research and development support	758	4
Total revenues	38,078	15,706
Expenses:		
Research and development	44,282	34,413
Selling, general and administrative	16,648	10,209
Total operating expenses	60,930	44,622
Loss from operations	(22,852)	(28,916)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(1,249)	(4,644)
Interest expense on convertible bonds	-	(24)
Other loss, net	(44)	(467)
Net loss	$ (24,145)	$ (34,051)
Basic and diluted net loss per common share	$ (0.10)	$ (0.17)
Basic and diluted weighted average common shares outstanding	253,263	198,835