

IMMUNOGEN INC

FORM 8-K

(Current report filing)

Filed 01/27/12 for the Period Ending 01/27/12

Address	830 WINTER ST WALTHAM, MA 02451
Telephone	(781)895-0600
CIK	0000855654
Symbol	IMGN
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	06/30

**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): **January 27, 2012**

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))
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ITEM 2.02 — RESULTS OF OPERATION AND FINANCIAL CONDITION

On January 27, 2012, ImmunoGen, Inc. (Nasdaq: IMGN) issued a press release to announce the company's financial results for the quarter ended December 31, 2011. The press release announcing financial results for the quarter ended December 31, 2011 is included as Exhibit 99.1 and incorporated herein by reference.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(d): The following exhibit is being furnished herewith:

<u>Exhibit No.</u>	<u>Exhibit</u>
99.1	Press Release of ImmunoGen, Inc. dated January 27, 2012

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: January 27, 2012

/s/ Gregory Perry _____

Gregory Perry
Senior Vice President and Chief Financial Officer

IMMUNOGEN, INC.

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ImmunoGen, Inc. Reports Second Quarter Fiscal Year 2012 Financial Results and Provides Quarterly Update

- *Product pipeline progress includes continued advancement of trastuzumab emtansine (T-DM1) toward Phase III data reporting and marketing submission in 2012, initiation of SAR3419 multi-study Phase II program; and progression of IMGN901 toward Phase II start.*
- *The product pipeline continues to expand through progress by both ImmunoGen and partners.*
- *Company's balance sheet further strengthened by \$25 million from newest collaboration and progress by existing partners.*

WALTHAM, MA, January 27, 2012 — ImmunoGen, Inc. (Nasdaq: IMGN), a biotechnology company that develops targeted anticancer products using its antibody expertise and Targeted Antibody Payload (TAP) technology, today reported financial results for the three-month period ended December 31, 2011 — the second quarter of the Company's 2012 fiscal year.

“In the past three months, there have been meaningful advances in both the depth and the breadth of our product pipeline,” commented Daniel Junius, President and CEO. “Among the lead compounds, Roche continues to expect the first trastuzumab emtansine Phase III data presentation and marketing submissions in 2012. Roche now also expects to provide an update on its plans in early stage breast cancer in mid-2012. Sanofi has advanced SAR3419 into Phase II testing, and we're close to finalizing the dose needed to initiate Phase II testing of our IMGN901 compound.”

Mr. Junius continued, “We remain on track for two additional ImmunoGen compounds — IMGN529 and IMGN853 — to be in the clinic in the coming months. Our next wholly owned product candidate is advancing just a year behind IMGN853. Our partners also continue to make progress, with two Amgen TAP compounds now having active INDs,

patient dosing underway with Bayer's BAY 94-9343, and BT-062, SAR650984, and SAR566658 continuing to progress."

Continued Progress with Lead Product Programs

Trastuzumab emtansine— Comprises the HER2-targeting antibody, trastuzumab, and ImmunoGen's TAP technology; in global development by Roche.

- For HER2+ metastatic breast cancer — Roche is evaluating trastuzumab emtansine for second-line, first-line, and third-line treatment of HER2+ metastatic breast cancer in its EMILIA, MARIANNE and TH3RESA Phase III trials, respectively.

Roche continues to expect to report EMILIA data in 2012 and to use this trial to apply in 2012 for marketing approval of trastuzumab emtansine in the US and Europe. Chugai, a member of the Roche Group, expects to apply for marketing approval in Japan in 2013. Roche continues to expect to apply for marketing approval for first-line use in 2014 using MARIANNE data and recently noted its intention of applying for approval of trastuzumab emtansine used alone and in combination with pertuzumab for this use. No regulatory submission projections have yet been made for TH3RESA, which started in the past six months.

- For early stage HER2+ breast cancer — Roche reported in late 2011 that it had completed patient enrollment in its Phase II trial assessing trastuzumab emtansine safety in the adjuvant/neoadjuvant setting and that it expects to provide an update on its plans for early stage breast cancer in mid-2012.
- For HER2+ gastric cancer — Promising preclinical data have been reported with the compound for this use, with more information on development plans expected.

Lorvotuzumab mertansine (IMGN901)— Wholly owned ImmunoGen TAP compound for small-cell lung cancer (SCLC) and other CD56+ cancers.

- Patient dosing in the randomized Phase II trial evaluating IMGN901 for first-line treatment of SCLC is expected to begin in late 1Q/early 2Q 2012. The dose is being finalized in Phase I.
- Patient enrollment continues in a Phase I trial assessing the compound for multiple myeloma.

SAR3419— CD19-targeting TAP compound created by ImmunoGen and licensed to Sanofi in a broader collaboration.

- Phase II trials are now in process that evaluate SAR3419: (1) as a single agent for diffuse large B-cell lymphoma (DLBCL); (2) in combination with Rituxan® (rituximab) for DLBCL; and (3) as a single agent for B-cell acute lymphoblastic leukemia (B-ALL). The SAR3419 Phase II program is designed to support rapid advancement to pivotal

testing.

- Clinical data are expected to be reported at a mid-year medical conference from the Phase I trial establishing the optimized dosing schedule being used in Phase II.

Expanding Clinical Pipeline

In September 2011, patient dosing began with BAY 94-9343, a mesothelin-targeting conjugate developed by Bayer HealthCare under a TAP technology license with ImmunoGen. Two other TAP compounds advanced to active IND stage in November 2011 through ImmunoGen's collaboration with Amgen. Additionally, the clinical compounds BT-062, SAR650984 and SAR566658 continue to progress through the Company's collaborations with Biotest and Sanofi (two), respectively.

Two wholly owned ImmunoGen compounds are expected to begin clinical testing in the coming months:

- IMGN529 — This innovative compound for non-Hodgkin's lymphoma (NHL) and chronic lymphocytic leukemia utilizes ImmunoGen's TAP technology with an antibody that, in preclinical testing, demonstrated meaningful anticancer activity of its own. Phase I testing of IMGN529 in NHL is expected to begin in early 2012.
- IMGN853 — This unique folate-targeting compound is a potential treatment for ovarian cancer and other carcinomas that over-express folate receptor 1. IMGN853 remains on track to advance to active IND stage by mid-2012. This TAP compound utilizes a linker developed by ImmunoGen scientists to counteract cancer cell multi-drug resistance mechanisms.

Financial Guidance and Results

ImmunoGen's financial guidance remains unchanged from that issued in December 2011 when the Company entered into a collaboration agreement with Eli Lilly and Company. ImmunoGen expects its net loss for its fiscal year ending June 30, 2012 to be between \$78-82 million. Net cash used in operations is expected to be between \$40 and \$45 million and cash and marketable securities at its fiscal year end of June 30, 2012 are expected to total between \$145 and \$150 million.

ImmunoGen's business model is to develop significant new anticancer compounds and to help fund its product programs by selectively outlicensing its TAP technology. The Company has received more than \$300 million in cash from partnerships over the past ten years.

"The financial benefit of our business model is evident in this quarter's results," commented Gregory Perry, Executive Vice President and CFO. "The \$25 million from our newest collaboration and recent partner milestones helps ImmunoGen develop and advance our wholly owned product candidates while reducing our dependence on capital markets."

ImmunoGen reported a net loss of \$12.8 million, or \$0.17 per basic and diluted share, for the quarter ending December 31, 2011 (2Q FY2012), as compared to a net loss of \$14.2 million, or \$0.21 per basic and diluted share, for the same quarter of the last year (2Q FY2011).

Revenues were \$7.6 million for 2Q FY2012, as compared to \$4.2 million for the same period last year. Revenues in 2Q FY2012 include \$6.0 million of license and milestone fees and \$0.9 million of research and development support fees, compared to \$0.9 million and \$2.0 million respectively, for the same quarter last year. The 2Q FY2012 license and milestone fees include \$5.0 million in milestone payments earned with three clinical product achievements by two collaborative partners. Revenues in 2Q FY2012 also include \$0.6 million of clinical material reimbursement, compared to \$1.3 million for 2Q FY2011.

Operating expenses for 2Q FY2012 were \$20.4 million, compared to \$19.7 million in the same period last year. Operating expenses in 2Q FY2012 include research and development expenses of \$15.6 million, compared to \$16.0 million in 2Q FY2011. Increased personnel expenses — including increased stock compensation expense — in support of internal programs in the current quarter were offset relative to the prior year period by reduced expenses related to clinical material supply for ImmunoGen and partner programs. The operating expenses also include general and administrative expenses of \$4.8 million in 2Q FY2012, compared to \$3.7 million in 2Q FY2011. This increase is primarily due to increased patent costs and personnel expenses, particularly stock compensation expense.

Other income, net, was \$23,000 in 2Q FY2012 as compared to \$1.3 million for the same period last year. The prior year period included \$1.2 million of federal grant funding the Company was awarded under the Patient Protection and Affordable Care Act of 2010 to develop new anticancer therapies.

ImmunoGen had approximately \$168.4 million in cash and cash equivalents as of December 31, 2011, compared with \$191.2 million as of June 30, 2011, and had no debt outstanding in either period. Not included in the December 31, 2011 cash balance is the \$20 million upfront payment due from Lilly — it was recorded in accounts receivable and received in January 2012. Cash used in operations was \$24.0 million in the first six months of FY2012, compared with \$18.4 million of cash provided by operations in the same period in FY2011. The prior year period includes the \$45 million upfront payment from the collaboration established with Novartis in October 2010. Capital expenditures were \$0.8 million and \$0.9 million for the first six months of FY2012 and FY2011, respectively.

About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer therapeutics using the Company's expertise in tumor biology, monoclonal antibodies, potent cancer-cell killing agents and engineered linkers. The Company's TAP technology uses monoclonal antibodies to deliver one of ImmunoGen's proprietary cancer-cell killing agents specifically to tumor cells. There are now numerous TAP compounds in clinical development with a wealth of clinical data

reported. ImmunoGen's collaborative partners include Amgen, Bayer HealthCare, Biotest, Lilly, Novartis, Roche, and Sanofi. The most advanced compound using ImmunoGen's TAP technology, trastuzumab emtansine (T-DM1), is in Phase III testing through the Company's collaboration with Genentech, a member of the Roche Group. More information about ImmunoGen can be found at www.immunogen.com.

Rituxan® is a registered trademark of Biogen Idec.

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 net loss, cash used in operations and capital expenditures in its 2012 fiscal year; its cash and marketable securities as of June 30, 2012; the occurrence, timing and outcome of potential pre-clinical, clinical and regulatory events related to the Company's and its collaboration partners' product programs; and the presentation of preclinical and clinical data on the Company's and collaboration partners' 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 and the Company's collaboration partners' research 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; ImmunoGen's ability to financially support its product programs; ImmunoGen's dependence on collaborative partners; industry merger and acquisition activity; and other factors more fully described in ImmunoGen's Annual Report on Form 10-K for the fiscal year ended June 30, 2011 and other reports filed with the Securities and Exchange Commission.

-Financials Follow-

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

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	December 31, 2011	June 30, 2011
ASSETS		
Cash and cash equivalents	\$ 168,372	\$ 191,206
Other assets	39,847	26,435
Total assets	\$ 208,219	\$ 217,641
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities	\$ 11,620	\$ 14,566
Long-term portion of deferred revenue and other long-term liabilities	81,255	63,106
Shareholders' equity	115,344	139,969
Total liabilities and shareholders' equity	\$ 208,219	\$ 217,641

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2011	2010	2011	2010
Revenues:				
License and milestone fees	\$ 6,025	\$ 866	\$ 7,212	\$ 2,676
Research and development support	945	2,005	2,013	3,500
Clinical materials reimbursement	647	1,307	928	1,413
Total revenues	7,617	4,178	10,153	7,589
Expenses:				
Research and development	15,559	16,004	32,720	29,429
General and administrative	4,834	3,688	9,675	7,052
Total operating expenses	20,393	19,692	42,395	36,481
Loss from operations	(12,776)	(15,514)	(32,242)	(28,892)
Other income, net	23	1,281	6	1,771
Loss before taxes	(12,753)	(14,233)	(32,236)	(27,121)
Provision for income taxes	—	—	—	—
Net loss	\$ (12,753)	\$ (14,233)	\$ (32,236)	\$ (27,121)
Net loss per common share, basic and diluted	\$ (0.17)	\$ (0.21)	\$ (0.42)	\$ (0.40)
Weighted average common shares outstanding, basic and diluted	76,523	67,965	76,443	67,961