

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

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FILER

IMMUNOGEN INC

CIK: **855654** | IRS No.: **042726691** | State of Incorpor.: **MA** | Fiscal Year End: **0630**
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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): **August 12, 2004**

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.)

128 Sidney Street, Cambridge, MA 02139
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(617) 995-2500**

ITEM 7. FINANCIAL STATEMENTS, PRO FORMA FINANCIAL INFORMATION AND EXHIBITS

(c) Exhibits

<u>Exhibit No.</u>	<u>Exhibit</u>
99.1	Press Release of ImmunoGen, Inc. dated August 12, 2004

This press release is being furnished pursuant to Item 12 of this Current Report on Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

ITEM 12. DISCLOSURE OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On August 12, 2004, ImmunoGen, Inc. issued a press release to report the company's financial results for the three and twelve months ended June 30, 2004. A copy of the press release is attached to this current report on Form 8-K as Exhibit 99.1.

The information shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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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: August 12, 2004

/s/ Virginia A. Lavery

Virginia A. Lavery

Vice President, Finance and Treasurer

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EXHIBIT INDEX

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IMMUNOGEN, INC.

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A live conference call and webcast are scheduled for August 12, 2004 at 4:30 p.m. ET.

To access the live conference call by phone, dial 913-981-4900. No passcode is required. A playback of the call will be available from approximately 7:30 p.m. on August 12 through 11:59 p.m. on August 18, 2004. To listen to the playback, call 719-457-0820 and provide passcode 586347.

The call also may be heard through the "Investor Relations" section on ImmunoGen's website, <http://www.immunogen.com>. Following the live webcast, a replay of the call will be available at the same location until August 18, 2004.

FOR IMMEDIATE RELEASE**ImmunoGen, Inc. Reports Fourth Quarter and Fiscal Year 2004 Financial Results****– Revenue from Partners Increased Substantially over 2003 Levels –**

CAMBRIDGE, MA, August 12, 2004 – ImmunoGen, Inc. (Nasdaq: IMGN) today announced financial results for the three- and twelve-month periods ended June 30, 2004. For the three-month period, the Company reported net income of \$302,000, or \$0.01 per basic and diluted share, compared to a net loss of \$6.9 million, or \$(0.17) per basic and diluted share, in the same three-month period last year. For the fiscal year ended June 30, 2004, the Company reported a net loss of \$5.9 million, or \$(0.15) per basic and diluted share, compared to a net loss of \$20 million, or \$(0.48) per basic and diluted share, for the fiscal year ended June 30, 2003.

Revenues for the fiscal year ended June 30, 2004 were \$26.0 million compared to \$7.6 million for the fiscal year ended June 30, 2003. Revenues for the 2004 fiscal year include \$13.6 million of research and development support fees earned since September 1, 2003 pursuant to the Company's discovery, research and commercialization collaboration with Aventis. Also included in these revenues was \$6.6 million of clinical material reimbursement related to the manufacture of clinical materials under certain collaborative agreements compared to \$3.2 million for the 2003 fiscal year.

– more –

Total operating expenses for the fiscal year ended June 30, 2004 were \$34.5 million as compared to \$32.2 million for the fiscal year ended June 30, 2003. Included in the operating expenses for the 2004 and 2003 fiscal years were costs of clinical material reimbursement of \$5.7 million and \$2.8 million, respectively. Also included in total operating expenses for the 2004 fiscal year was research and development expense of \$22.2 million compared to research and development expense of \$23.4 million for the 2003 fiscal year.

Other income decreased to \$2.7 million in the fiscal year ended June 30, 2004 compared to \$4.6 million for the fiscal year ended June 30, 2003. Included in other income for the 2004 and 2003 fiscal years was interest income of \$1.4 million and \$2.7 million, respectively. The decrease in interest income for the 2004 fiscal year is attributable to a lower average cash balance and reduced return on investments as compared to fiscal year 2003. Also included in other income for the 2004 fiscal year is \$1.3 million, representing the reimbursement from Aventis of manufacturing expense for antibody; approximately \$531,000 of this expense was included in research and development expense in the 2003 fiscal year.

The net income reported for the three months ended June 30, 2004 was due primarily to the timing and amount of fees and clinical material reimbursements recorded from partners during the period, and should not be interpreted as an indication that the Company will be profitable on a quarter-to-quarter basis.

As of June 30, 2004, ImmunoGen had approximately \$94.6 million in cash and marketable securities. This compares to \$101.3 million as of June 30, 2003. During the year ended June 30, 2004, cash used in operations was \$5.0 million compared to \$21.9 million in the year ended June 30, 2003. The Company anticipates that its current capital resources plus future collaborator payments, including committed funding to be received from Aventis pursuant to the collaboration agreement, will enable the Company to meet its operational expenses and capital expenditures for at least the next three to five fiscal years.

Total assets increased to \$122.6 million as of June 30, 2004, compared to \$118.0 million as of June 30, 2003. The increase is attributable primarily to an increase in unbilled revenue related to research and development support fees earned but not yet billable pursuant to the terms of the Company's discovery, research and commercialization collaboration with Aventis and to an increase in inventory related to the timing of the manufacture and shipment of conjugate produced for the Company's other collaborators, offset by a decrease in cash and marketable securities used to fund operations. Total liabilities increased to \$25.5 million as of June 30, 2004 compared to \$15.4 million at June 30, 2003. The increase in liabilities is attributable primarily to the \$12.0 million upfront payment received from Aventis that the Company deferred and records as revenue ratably over the expected term of the research collaboration.

Mitchel Sayare, Ph.D., Chairman and CEO, commented, "Our favorable financial performance is a direct result of our business model, which is to use technology and product out-license arrangements to provide us with cash while we develop and advance our own proprietary products. Revenues from our partnerships increased substantially in 2004. This was largely because of our collaboration with Aventis, but we also earned more revenue from our other out-license partners as we manufactured more clinical-grade materials for their advancing clinical programs. The cash we received from our partners helped us achieve a total cash operating burn rate of \$5 million for our 2004 fiscal year."

Dr. Sayare continued, "We expect to initiate an additional huN901-DM1 clinical trial - one to assess its clinical utility in a hematologic malignancy - within the next six months and to initiate our cantuzumab mertansine clinical program shortly thereafter. Support for the

advancement of partner compounds currently in clinical testing as well as the entry of additional partner compounds into clinical testing will also be a big part of our programs going forward. Consequently, we have established our own in-house clinical department, strengthened our regulatory department, expanded manufacturing-related functions, and enhanced our alliance management function. We are committed to demonstrating the clinical utility of our proprietary compounds and to helping our partners achieve success with their compounds."

ImmunoGen's proprietary Tumor-Activated Prodrug (TAP) technology uses tumor-targeting antibodies to deliver a potent cell-killing agent specifically to cancer cells. The cell-killing agent in all TAP compounds now in clinical testing is DM1, developed by ImmunoGen specifically for antibody-directed delivery to cancer cells.

Update on ImmunoGen's Clinical-Stage Compounds

[huN901-DM1](#) - huN901-DM1 targets the CD56 antigen found on small-cell lung cancer (SCLC), other cancers of neuroendocrine origin, and certain hematologic malignancies.

ImmunoGen now has gained ownership of the huN901-DM1 IND from former partner Vernalis, and on July 1, 2004, ImmunoGen assumed control of the Phase I/II SCLC study underway in the United States from Vernalis. ImmunoGen is taking steps to expedite the completion of this study. Vernalis remains responsible for the Phase I SCLC study it initiated in the United Kingdom. In 2000, ImmunoGen licensed certain international marketing rights for huN901-DM1 to British Biotech, which was required to develop the compound for the U.S. as well. ImmunoGen regained all rights to the compound after British Biotech became part of Vernalis and was downsized.

ImmunoGen plans to initiate a clinical study with huN901-DM1 in the treatment of CD56-positive hematologic malignancies, including multiple myeloma, to complement the two solid tumor malignancy studies underway. In July 2004, preclinical data were published in *Cancer Research* that showed that huN901-DM1 can selectively target and kill CD56-positive multiple myeloma cells, and that the compound can kill these cancer cells even when they are in the presence of bone marrow stromal cells (BMSC). There is evidence that multiple myeloma cells adhering to BMSC are resistant to standard chemotherapeutic agents.

Cantuzumab mertansine - This compound targets the CanAg antigen found on colorectal, pancreatic, gastric and other abdominal cancers as well as on many non-small-cell lung cancers.

In July 2004, data from the second cantuzumab mertansine Phase I study were published in *Clinical Cancer Research*. The findings from the full dataset are consistent with those previously reported for the first 27 patients enrolled: cantuzumab mertansine was found to have a maximum tolerated dose of 115 mg/m² when dosed weekly and to demonstrate evidence of biological activity.

ImmunoGen plans to provide details on its cantuzumab mertansine study plans later this year and to initiate testing to establish the clinical utility of the compound shortly thereafter.

Update on Partner-Developed TAP Compounds

Two partner-developed TAP compounds have advanced into clinical testing: MLN2704 and bivatuzumab mertansine. MLN2704, developed by Millennium Pharmaceuticals, Inc., targets the prostate-specific membrane antigen (PSMA); bivatuzumab mertansine, developed by Boehringer Ingelheim, targets CD44v6.

The first clinical data for partner-developed TAP compound, MLN2704 were reported at the American Society of Clinical Oncology (ASCO) meeting in June 2004. These were from an MLN2704 Phase I study using a dose escalation design: dosage was increased in new groups of patients if the lower dosage previously administered was not associated with dose-limiting toxicity. The study patients had androgen-independent prostate cancer that had metastasized.

MLN2704 dosing was started at 18 mg/m² and, after nine escalations, reached 343 mg/m². Even at this dosage, there was insufficient toxicity to establish the maximum tolerated dose. No patient stopped treatment because of adverse events.

Six patients received 343 mg/m² and three patients received 264 mg/m², the second highest dose administered. Among these nine “highest dose” patients, two had marked (>50%), sustained reductions in their PSA levels and two more had PSA level stabilization. A rising PSA level is an indicator of progression of prostate cancer.

Four of these nine “highest dose” patients had tumors that could be quantified. Among these four patients, one experienced a sustained partial response by RECIST criteria and two had stable disease. At the time of the ASCO presentation, the patient with the sustained partial response had received MLN2704 once every four weeks for 46 weeks without disease progression.

Millennium also has a Phase I/II study underway in a comparable patient population that compares dosing MLN2704 weekly versus once every two weeks.

About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer biopharmaceuticals. The Company's proprietary TAP technology uses tumor-targeting antibodies to deliver a potent cell-killing agent specifically to cancer cells. Two ImmunoGen-developed TAP products have begun clinical evaluation: cantuzumab mertansine and huN901-DM1. ImmunoGen out-licenses its TAP technology in exchange for upfront, milestone, and manufacturing payments plus royalties. Companies developing products using ImmunoGen's TAP technology include Boehringer Ingelheim (bivatuzumab mertansine), Millennium Pharmaceuticals (MLN2704), and Genentech (Trastuzumab-DM1); ImmunoGen also has multitarget agreements with Genentech, Abgenix, and Millennium. ImmunoGen and Aventis have a collaboration to discover, develop, and commercialize antibody-based anticancer therapeutics. The agreement provides ImmunoGen with committed funding and also includes milestone payments, royalties, and co-promotion rights.

This press release includes forward-looking statements based on management's current expectations. 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 the Company'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 outcome of the Company's research and clinical development processes, including the anticipated advancement into the next stages of clinical testing of cantuzumab mertansine and huN901-DM1; the outcome of the Company's collaboration partners' research and clinical development processes, including the anticipated clinical advancement of partner compounds; the difficulties inherent in the development of pharmaceuticals, including uncertainties as to the timing, expense and results of preclinical studies and clinical trials; the Company's dependence upon existing and potential collaborative partners, and the outcome of the clinical testing of TAP compounds being developed by the Company's existing partners; uncertainty as to whether the Company's potential products or those of the Company's collaborators will succeed in entering human clinical trials and uncertainty as to the results of such trials; the ability of the Company's current capital resources and anticipated future collaborator payments to enable the Company to meet its current and projected operational expenses and capital expenditures for the next three to five years; the risk that the Company and/or its collaborators may not be able to obtain regulatory approvals necessary to commercialize their product candidates; the potential development by competitors of competing products and technologies; uncertainty whether the Company's TAP technology will produce safe, effective and commercially viable products; and other factors more fully described in ImmunoGen's Annual Report on Form 10-K for the fiscal year ended June 30, 2003 and other reports filed with the Securities and Exchange Commission.

- financials follow -

ImmunoGen, Inc. Fourth Quarter and Fiscal Year 2004 Financial Results

IMMUNOGEN, INC.

SELECTED FINANCIAL INFORMATION

(in thousands, except per share amounts)

CONDENSED CONSOLIDATED BALANCE SHEETS

As of June 30, 2004 and June 30, 2003

	June 30, 2004	June 30, 2003
ASSETS		
Cash and marketable securities	\$ 94,610	\$ 101,273
Other assets	28,020	16,759

Total assets	\$ 122,630	\$ 118,032
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LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities	\$ 11,285	\$ 5,696
Long term portion of deferred revenue and other long term liabilities	14,208	9,657
Stockholders' equity	97,137	102,679
Total liabilities and stockholders' equity	\$ 122,630	\$ 118,032

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

For the three months and year ended June 30, 2004 and 2003

	Three Months Ended		Year Ended	
	June 30,		June 30,	
	2004	2003	2004	2003
	(unaudited)	(unaudited)		
Revenues:				
Research and development support	\$ 4,409	\$ -	\$ 13,563	\$ -
License fees and milestone payments	1,300	438	5,548	4,183
Clinical materials reimbursement	3,460	903	6,571	3,170
Development fees	143	8	274	275
Total revenues	9,312	1,349	25,956	7,628
Expenses:				
Cost of clinical materials reimbursed	2,944	799	5,659	2,834
Research and development	6,088	6,457	22,224	23,429
General and administrative	1,616	1,416	6,631	5,957
Total operating expenses	10,648	8,672	34,514	32,220
Loss from operations	(1,336)	(7,323)	(8,558)	(24,592)
Other income, net	1,659	464	2,687	4,645
Income (loss) before taxes	323	(6,859)	(5,871)	(19,947)
Income tax expense	21	-	46	35
Net income (loss)	\$ 302	\$ (6,859)	\$ (5,917)	\$ (19,982)
Net income (loss) per common share, basic	\$ 0.01	\$ (0.17)	\$ (0.15)	\$ (0.48)
Average common shares outstanding, basic	40,735	40,584	40,646	41,912
Net income (loss) per common share, diluted	\$ 0.01	\$ (0.17)	\$ (0.15)	\$ (0.48)
Average common shares outstanding, diluted	42,919	40,584	40,646	41,912

