# ImmunoGen, Inc. Reports Fourth Quarter and Fiscal Year 2009 Financial Results

# -Company Reports Meaningful Pipeline Progress with Proprietary and Partnered Product Candidates-

WALTHAM, Mass.--(BUSINESS WIRE)--Aug. 6, 2009-- ImmunoGen, Inc. (Nasdaq: IMGN), a biopharmaceutical company that develops targeted anticancer therapeutics using its antibody expertise and Targeted Antibody Payload (TAP) technology, today announced financial results for the fiscal year and three-month period ended June 30, 2009.

"There are now multiple compounds in the clinic generating data supportive of our TAP technology and the most advanced of these could potentially gain marketing approval in 2010," commented Daniel Junius, President and Chief Executive Officer. "This progress enables us to focus on building value through prompt advancement of our lead compounds, further expansion of our pipeline of proprietary products and leveraging our business development opportunities."

Mr. Junius continued, "We're now making clear progress with our IMGN901 compound – we recently reported encouraging new clinical data in solid tumors and, in multiple myeloma, we've gained the dosing information needed to expand our single agent trial and to move forward to starting our combination trial. Our IMGN388 clinical trial also is proceeding at a strong pace. At the same time, we're using the findings in the clinic with the lead TAP compounds – ours and our partners' – to strengthen and expand our pipeline of earlier-stage compounds. Our expanding pipeline, together with our technology and expertise, provide us with a number of possible business development opportunities, some potentially in interesting new areas."

# **Recent Highlights**

- Clinical data for trastuzumab-DM1 (T-DM1) as a third-line treatment<sup>1</sup> for HER2-positive metastatic breast cancer are now expected to be available in the fourth quarter of 2009 rather than in the first quarter of 2010. Roche has indicated that, if compelling, these data would be used to support a T-DM1 marketing application in the US in 2010.
- Encouraging IMGN901 clinical findings in the treatment of small-cell lung cancer, Merkel cell carcinoma, and other CD56positive solid tumors were reported at the 13<sup>th</sup> World Conference on Lung Cancer.
- The maximum tolerated dose of IMGN901 was established in patients with multiple myeloma an essential step to the initiation of its evaluation as part of a combination regimen for this disease and also to its expanded assessment as a single agent.
- The first SAR3419 and BT-062 clinical data are expected to be reported in the fourth quarter of 2009.

## **Financial Results**

For the three-month period ended June 30, 2009, ImmunoGen reported a net loss of \$10.8 million, or \$0.21 per basic and diluted share, compared to a net loss of \$11.9 million, or \$0.27 per basic and diluted share, for the same period last year. For the fiscal year ended June 30, 2009, ImmunoGen reported a net loss of \$31.9 million, or \$0.63 per basic and diluted share, compared to a net loss of \$32.0 million, or \$0.75 per basic and diluted share, for the fiscal year ended June 30, 2008.

For the fiscal year ended June 30, 2009, revenues were \$28.0 million, compared to \$40.2 million for the fiscal year ended June 30, 2008. Revenues for the 2009 fiscal year include \$15.1 million of license and milestone fees, compared to \$13.2 million for fiscal 2008. The license and milestone fees for the 2009 fiscal year include a \$6.5 million milestone payment earned from Genentech with the start of T-DM1 Phase III testing and a \$4.0 million milestone payment earned with sanofi-aventis' initiation of AVE1642 Phase II testing as well as other, smaller, items. The license and milestone fees for the 2009 fiscal year also include \$5.3 million of clinical material reimbursement, compared to \$12.1 million for fiscal 2008. The lower amount for fiscal 2009 compared with fiscal 2008 is primarily because in fiscal 2008 this revenue included \$5.0 million associated with the Company supplying a collaborator with one of its cytotoxic agents and because more clinical material batches were released in fiscal 2008 than in fiscal 2009. Revenues for the 2009 fiscal year also include \$7.6 million of research and development support fees, compared to \$15.0 million for fiscal 2008. The decreased funding in the current year compared to the prior year is primarily due to a reduction in the amount earned from sanofi-aventis with the conclusion of its committed funding obligations in calendar 2008.

Operating expenses for the fiscal year ended June 30, 2009 were \$59.8 million, compared to \$74.4 million for the fiscal year ended June 30, 2008. Operating expenses for the 2009 fiscal year include research and development expenses of \$45.9 million, compared to \$60.0 million for fiscal 2008. The decrease in research and development expenses for fiscal 2009 versus the prior year is primarily due to reduced cost of clinical materials reimbursed, decreased antibody development and

supply costs, and reduced development costs incurred with contract manufacturing organizations related to the potential production of later-stage materials, partially offset by greater salaries and related expenses and by lower overhead utilization. Operating expenses for the 2009 fiscal year also include general and administrative expenses of \$13.9 million, compared to \$14.3 million for the 2008 fiscal year.

Other (expense)/income, net, consisting primarily of interest income, (losses)/gains recognized on forward contracts and losses realized on investments due to impairment, was \$(0.2) million in the fiscal year ended June 30, 2009, compared to \$2.1 million for the fiscal year ended June 30, 2008. Included in other (expense)/income, net, was \$0.6 million and \$2.2 million of interest income and \$(0.2) million and \$0.7 million

of (losses)/gains recognized on forward contracts for fiscal 2009 and 2008, respectively. Losses realized on investments due to impairment were (\$0.5) million in both years.

ImmunoGen had approximately \$71.1 million in cash and marketable securities as of June 30, 2009, inclusive of net proceeds of \$38.0 million raised in June 2009 with the sale of common equity through a public offering, compared with \$47.9 million as of June 30, 2008. The Company had no debt outstanding in either period. During fiscal 2009, cash used in operations was \$13.3 million, compared to \$20.1 million in fiscal 2008. Proceeds from the landlord for a tenant allowance benefited these amounts in fiscal 2009 and 2008 by \$0.8 million and \$10.0 million, respectively. Capital expenditures were \$1.9 million and \$18.0 million for the fiscal years ended June 30, 2009 and 2008, respectively. Capital expenditures for the prior year included \$3.7 million for improvement of the Company's capabilities at its manufacturing plant in Norwood, MA and \$10.8 million under a tenant allowance to build out the laboratory and office space at the Waltham, MA facility.

#### **Financial Guidance**

ImmunoGen expects its net loss for its fiscal year ending June 30, 2010 to be between \$44-47 million, its cash used in operations to be between \$32-35 million and its capital expenditures to be between \$1-2 million. Cash and marketable securities at June 30, 2010 are anticipated to be between \$38-40 million.

"As we look out over the next few years, we expect our cash use to peak in our 2010 fiscal year," commented Gregory Perry, Senior Vice President and Chief Financial Officer. "This is because, while overall fiscal 2010 expenses are expected to be comparable to those in fiscal 2009, we currently do not expect fiscal 2010 milestones and research support funding to reach last year's levels. We expect greater milestone payments and potentially growing royalty revenue to benefit our financial results beginning in fiscal 2011. Additionally, we believe we have a range of business development opportunities that can create value and provide non-dilutive sources of cash that potentially would enhance our cash generation in fiscal 2010 and beyond."

## UPDATE ON THE CLINICAL-STAGE ANTICANCER COMPOUNDS

## Trastuzumab-DM1 (T-DM1)

T-DM1 consists of ImmunoGen's DM1 cancer-cell killing agent linked to the HER2-binding antibody, trastuzumab, and is in development by Genentech and Roche.

- Encouraging T-DM1 (non-pivotal) clinical data were reported at the ASCO annual meeting in May 2009.
- Roche projected in July 2009 that clinical data from the Phase II trial evaluating T-DM1 as a third-line treatment<sup>1</sup> for HER2-positive metastatic breast cancer (HER2+ MBC) will be available in the fourth quarter of 2009. Roche also noted the potential submission of a regulatory filing in 2010 for marketing approval of T-DM1 for this use.
- T-DM1, given as a single agent, also is being evaluated as a second-line treatment<sup>2</sup> for HER2+ MBC in a Phase III trial and as a first-line treatment for this cancer in a Phase II trial.
- Patient enrollment is underway in early-stage clinical trials evaluating T-DM1 used in combination with docetaxel (Taxotere®) and used in combination with pertuzumab. A trial assessing T-DM1 used in combination with GDC-0941 is planned.

#### IMGN901

This ImmunoGen TAP compound is in development for the treatment of CD56+ cancers.

- Encouraging clinical findings with IMGN901 for CD56+ solid tumors were presented at the 13<sup>th</sup> World Conference on Lung Cancer.
- Updated clinical data with IMGN901 for CD56+ multiple myeloma (MM) are expected to be reported in the fourth quarter of 2009. These are expected to include new findings related to the durability of responses to treatment with IMGN901

among patients whose MM has progressed on multiple prior therapies.

- The maximum tolerated dose (MTD) has been established with IMGN901 when used alone to treat MM. IMGN901 can now
  be dosed at its MTD in an expanded number of patients with recurrent MM.
- ImmunoGen intends to initiate a Phase I clinical trial evaluating IMGN901 used in combination with lenalidomide (Revlimid®) plus dexamethasone in September/ October 2009.

#### SAR3419

SAR3419 consists of ImmunoGen's DM4 cancer-cell killing agent linked to a CD19-binding antibody that was developed and humanized by ImmunoGen. SAR3419 is being developed for the treatment of non-Hodgkin's lymphoma by sanofi-aventis.

• The first SAR3419 clinical findings are expected to be reported in the fourth quarter of 2009.

#### IMGN388, BT-062 and BIIB015

These are the most recent TAP compounds to enter clinical testing. IMGN388 is in development by ImmunoGen, while BT-062 and BIIB015 are in development by Biotest and Biogen Idec, respectively.

• The first BT-062 clinical findings are expected to be reported in the fourth quarter of 2009.

#### About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer therapeutics using its expertise in cancer biology, monoclonal antibodies and the creation and attachment of potent cell-killing agents. The Company's TAP technology uses antibodies to deliver one of ImmunoGen's proprietary cell-killing agents specifically to cancer targets. In addition to the Company's product pipeline, compounds utilizing the TAP technology are in clinical testing through ImmunoGen's collaborations with Genentech (a wholly-owned member of the Roche Group), sanofi-aventis, Biogen Idec and Biotest. The most advanced compound, T-DM1, is in Phase III testing being conducted by Genentech and Roche. Other ImmunoGen collaborative partners include Bayer HealthCare and Amgen.

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 2010 fiscal year; its cash and marketable securities as of June 30, 2010; the advancement of trastuzumab-DM1 (T-DM1); the Company's and its collaboration partners' clinical trial activity and presentation of clinical data; and the Company's partnering activities. 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 outcome of ImmunoGen's research and clinical development processes; the outcome of ImmunoGen's collaboration partners; research and clinical development processes of potential collaboration partners; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense and results of preclinical studies and clinical trials; 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, 2008 and other reports filed with the Securities and Exchange Commission.

Taxotere® is a registered trademark of sanofi-aventis. Revlimid® is a registered trademark of Celgene Corporation.

<sup>1</sup> Patients must have had prior treatment with at least two lines of anti-HER2 therapy in the metastatic setting, and must have received an anthracycline, a taxane, trastuzumab, lapatinib and capecitabine in the neoadjuvant, adjuvant, locally advanced or metastatic setting.

<sup>2</sup> Patients must have received prior treatment that included both a taxane (alone or in combination with another agent) and trastuzumab in the adjuvant, locally advanced or metastatic setting.

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

# (Unaudited)

	June 30, 2009		June 30, 2008	
ASSETS				
Cash, cash equivalents and marketable securities Other assets	\$	71,125 29,579	\$	47,871 35,467
Total assets	\$	100,704	\$	83,338
LIABILITIES AND SHAREHOLDERS' EQUITY				
Current liabilities Long-term portion of deferred revenue and other long-term liabilities Shareholders' equity	\$	11,128 22,719 66,857	\$	10,386 17,653 55,299
Total liabilities and shareholders' equity	\$	100,704	\$	83,338

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(onauditeu)		iths Ended e 30,	Year Ended June 30,		
	2009	2008	2009	2008	
Revenues:					
License and milestone fees	\$ 814	\$ 1,060	\$ 15,117	\$ 13,156	
Clinical materials reimbursement	2,320	49	5,305	12,058	
Research and development support	1,168	3,374	7,566	15,035	
Total revenues	4,302	4,483	27,988	40,249	
Expenses:					
Research and development	11,663	12,739	45,904	60,013	
General and administrative	3,458	3,722	13,900	14,348	
Total operating expenses	15,121	16,461	59,804	74,361	
Loss from operations	(10,819)	(11,978)	(31,816)	(34,112)	
Other (expense)/income, net	(8)	55	(221)	2,119	
Loss before taxes	(10,827)	(11,923)	(32,037)	(31,993)	
Provision/(benefit) for income taxes		5	(100)	27	
Net loss	\$ (10,827)	<u>\$ (11,928)</u>	<u>\$(31,937)</u>	<u>\$(32,020)</u>	
Net loss per common share, basic and diluted	<u>\$ (0.21)</u>	<u>\$ (0.27)</u>	<u>\$ (0.63)</u>	<u>\$ (0.75)</u>	
Average common shares outstanding, basic and diluted	51,635	43,863	51,068	42,969	

Source: ImmunoGen, Inc.

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