

IMMUNOGEN INC  
Form 10-Q  
February 06, 2009  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

**x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES**  
**EXCHANGE ACT OF 1934**

**For the quarterly period ended December 31, 2008**

**OR**

**o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES**  
**EXCHANGE ACT OF 1934**

**For the transition period from            to**

**Commission file number 0-17999**

**ImmunoGen, Inc.**

Edgar Filing: IMMUNOGEN INC - Form 10-Q

**Massachusetts**  
(State or other jurisdiction of incorporation or  
organization)

**04-2726691**  
(I.R.S. Employer Identification No.)

**830 Winter Street, Waltham, MA 02451**

(Address of principal executive offices, including zip code)

**(781) 895-0600**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Shares of common stock, par value \$.01 per share: 51,034,440 shares outstanding as of January 29, 2009.

Table of Contents

IMMUNOGEN, INC.

FORM 10-Q

FOR THE QUARTER ENDED DECEMBER 31, 2008

TABLE OF CONTENTS

Item		Page Number
	<b>Part I</b>	
1.	<u>Financial Statements (Unaudited):</u>	3
1a.	<u>Consolidated Balance Sheets as of December 31, 2008 and June 30, 2008</u>	3
1b.	<u>Consolidated Statements of Operations for the three and six months ended December 31, 2008 and 2007</u>	4
1c.	<u>Consolidated Statements of Cash Flows for the three and six months ended December 31, 2008 and 2007</u>	5
1d.	<u>Notes to Consolidated Financial Statements</u>	6
2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
3.	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	27
4.	<u>Controls and Procedures</u>	27
	<b>Part II</b>	
1.	<u>Legal Proceedings</u>	29
1A.	<u>Risk Factors</u>	29
2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	29
3.	<u>Defaults Upon Senior Securities</u>	29
4.	<u>Submission of Matters to a Vote of Security Holders</u>	29
5.	<u>Other Information</u>	29
6.	<u>Exhibits</u>	30
	<u>Signatures</u>	31

Table of Contents**ITEM 1. Financial Statements****IMMUNOGEN, INC.****CONSOLIDATED BALANCE SHEETS****(UNAUDITED)****In thousands, except per share amounts**

	<b>December 31, 2008</b>	<b>June 30, 2008</b>
<b>ASSETS</b>		
Cash and cash equivalents	\$ 37,426	\$ 31,619
Marketable securities	8,485	16,252
Accounts receivable	1,885	396
Unbilled revenue	1,381	3,472
Inventory	480	2,116
Restricted cash	366	366
Prepaid and other current assets	2,684	1,820
Total current assets	52,707	56,041
Property and equipment, net of accumulated depreciation	21,332	22,751
Long-term restricted cash	4,460	4,508
Other assets	26	38
Total assets	\$ 78,525	\$ 83,338
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Accounts payable	\$ 2,402	\$ 1,411
Accrued compensation	3,225	1,164
Other accrued liabilities	2,969	4,304
Current portion of deferred lease incentive	979	935
Current portion of deferred revenue	3,374	2,572
Total current liabilities	12,949	10,386
Deferred lease incentive, net of current portion	10,030	10,052
Deferred revenue, net of current portion	11,113	5,293
Other long-term liabilities	3,259	2,308
Total liabilities	37,351	28,039
Commitments and contingencies (Note D)		
Shareholders' equity:		
Preferred stock, \$.01 par value; authorized 5,000 shares; no shares issued and outstanding		
Common stock, \$.01 par value; authorized 75,000 shares; issued and outstanding 50,890 and 50,778 shares as of December 31, 2008 and June 30, 2008, respectively	509	508
Additional paid-in capital	346,972	344,498
Accumulated deficit	(306,068)	(289,568)
Accumulated other comprehensive loss	(239)	(139)
Total shareholders' equity	41,174	55,299
Total liabilities and shareholders' equity	\$ 78,525	\$ 83,338

Edgar Filing: IMMUNOGEN INC - Form 10-Q

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents

## IMMUNOGEN, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

In thousands, except per share amounts

	Three Months Ended December 31,		Six Months Ended December 31,	
	2008	2007	2008	2007
<b>Revenues:</b>				
Research and development support	\$ 2,283	\$ 3,672	\$ 5,490	\$ 8,145
License and milestone fees	4,766	2,680	6,989	6,868
Clinical materials reimbursement	2,285	3,399	2,981	6,163
Total revenues	9,334	9,751	15,460	21,176
<b>Operating Expenses:</b>				
Research and development	12,888	13,158	24,748	23,992
General and administrative	3,521	3,527	7,199	5,951
Total operating expenses	16,409	16,685	31,947	29,943
Loss from operations	(7,075)	(6,934)	(16,487)	(8,767)
Other (expense) income, net	(129)	727	(113)	1,540
Loss before provision for income taxes	(7,204)	(6,207)	(16,600)	(7,227)
(Benefit) provision for income taxes	(101)	5	(100)	17
Net loss	\$ (7,103)	\$ (6,212)	\$ (16,500)	\$ (7,244)
Basic and diluted net loss per common share	\$ (0.14)	\$ (0.15)	\$ (0.32)	\$ (0.17)
Basic and diluted weighted average common shares outstanding	50,822	42,700	50,802	42,558

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents

## IMMUNOGEN, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

In thousands, except per share amounts

	Six months ended December 31,	
	2008	2007
Cash flows from operating activities:		
Net loss	\$ (16,500)	\$ (7,244)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	2,491	2,111
Loss on sale/disposal of fixed assets	2	11
Amortization of deferred lease incentive	(486)	(77)
Loss on sale of marketable securities	33	
Impairment of marketable securities	402	
Loss (gain) on forward contracts	182	(242)
Stock and deferred share unit compensation	2,226	1,085
Deferred rent	1,057	929
Changes in operating assets and liabilities:		
Accounts receivable	(1,489)	(207)
Unbilled revenue	2,091	1,741
Inventory	1,636	1,244
Prepaid and other current assets	(1,033)	(1,100)
Restricted cash	48	(3,777)
Other assets	12	63
Accounts payable	991	(58)
Accrued compensation	2,061	1,142
Other accrued liabilities	(1,473)	(2,393)
Deferred revenue	6,622	(663)
Proceeds from landlord for tenant improvements	750	550
Net cash used for operating activities	(377)	(6,885)
Cash flows from investing activities:		
Proceeds from maturities or sales of marketable securities	7,232	26,306
Reclassification of cash equivalent balance to marketable securities		(13,605)
Purchases of property and equipment, net	(1,037)	(5,311)
(Payments) proceeds from settlement of forward contracts	(279)	280
Net cash provided by investing activities	5,916	7,670
Cash flows from financing activities:		
Proceeds from stock options exercised	268	975
Net cash provided by financing activities	268	975
Net change in cash and cash equivalents	5,807	1,760
Cash and cash equivalents, beginning balance	31,619	10,605
Cash and cash equivalents, ending balance	\$ 37,426	\$ 12,365

Edgar Filing: IMMUNOGEN INC - Form 10-Q

The accompanying notes are an integral part of the consolidated financial statements.



Table of Contents

**IMMUNOGEN, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2008**

**A. Summary of Significant Accounting Policies**

*Basis of Presentation*

The accompanying unaudited consolidated financial statements at December 31, 2008 and June 30, 2008 and for the three and six months ended December 31, 2008, and 2007 include the accounts of ImmunoGen, Inc., or the Company, and its wholly-owned subsidiaries, ImmunoGen Securities Corp. and ImmunoGen Europe Limited. The consolidated financial statements include all of the adjustments, consisting only of normal recurring adjustments, which management considers necessary for a fair presentation of the Company's financial position in accordance with accounting principles generally accepted in the U.S. for interim financial information. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The preparation of interim financial statements requires the use of management's estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the interim financial statements and the reported amounts of revenues and expenditures during the reported period. The results of the interim periods are not necessarily indicative of the results for the entire year. Accordingly, the interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended June 30, 2008.

*Revenue Recognition*

The Company enters into licensing and development agreements with collaborative partners for the development of monoclonal antibody-based anticancer therapeutics. The Company follows the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin No. 104, *Revenue Recognition*, or SAB 104, and Emerging Issues Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Elements*, or EITF 00-21. In accordance with SAB 104 and EITF 00-21, the Company recognizes revenue related to research activities as they are performed, as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is probable. The terms of the Company's agreements contain multiple revenue elements which typically include non-refundable license fees, payments based upon the achievement of certain milestones and royalties on product sales. The Company evaluates such arrangements to determine if the deliverables are separable into units of accounting and then applies applicable revenue recognition criteria to each unit of accounting.

At December 31, 2008, the Company had the following three types of collaborative contracts with the parties identified below:

- License to use our TAP technology and/or certain other intellectual property to develop compounds to a single target antigen:

Biogen Idec Inc. (single-target license)

Biotest AG (single-target license)

Genentech, Inc. (multiple single-target licenses)

sanofi-aventis (license to multiple individual targets)

Bayer Healthcare AG (single-target license)

Table of Contents

- Option agreement for a defined period of time to secure licenses to use our TAP technology to develop anticancer compounds to a limited number of targets on established terms (broad option agreement):

Amgen, Inc.

Genentech, Inc.

sanofi-aventis

- Non-exclusive license to the Company's humanization technology:

sanofi-aventis

Generally, the forgoing collaboration agreements provide that the Company will (i) at the collaborator's request, manufacture and provide to them preclinical and clinical materials at the Company's cost, or, in some cases, cost plus a margin, (ii) earn payments upon the collaborators' achievements of certain milestones and (iii) earn royalty payments, generally until the later of the last applicable patent expiration or 12 years after product launch. Royalty rates may vary over the royalty term depending on certain intellectual property rights. The Company is required to provide technical training and to share any process improvements and know-how with its collaborators during the research term of the collaboration agreements.

Generally, upfront payments on single-target licenses are deferred over the period of the Company's substantial involvement during development. The Company's employees are available to assist the Company's collaborators during the development of their products. The Company estimates this development phase to begin at the inception of the collaboration agreement and conclude at the end of non-pivotal Phase II testing. The Company believes this period of involvement is, depending on the nature of the license, on average six and one-half years. Quarterly, the Company reassesses its periods of substantial involvement over which the Company amortizes its upfront license fees. In the event that a single-target license were to be terminated, the Company would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue at the date of such termination.

The Company defers upfront payments received from its broad option agreements over the period during which the collaborator may elect to receive a license. These periods are specific to each collaboration agreement, but are between seven and 12 years. If a collaborator selects an option to acquire a license under these agreements, any option fee is deferred and recorded over the life of the option, generally 12 to 18 months. If a collaborator exercises an option and the Company grants a single-target license to the collaborator, the Company defers the license fee and accounts for the fee as it would an upfront payment on a single-target license, as discussed above. Upon exercise of an option to acquire a license, the Company would recognize any remaining deferred option fee over the period of the Company's substantial involvement under the license acquired. In the event that a broad license agreement were to be terminated, the Company would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue at the date of such termination. In the event

## Edgar Filing: IMMUNOGEN INC - Form 10-Q

a collaborator elects to discontinue development of a specific product candidate under a single-target license, but retains its right to use the Company's technology to develop an alternative product candidate to the same target or a target substitute, the Company would cease amortization of any remaining portion of the upfront fee until there is substantial preclinical activity on another product candidate and the Company's remaining period of substantial involvement can be estimated.

When milestone fees are specifically tied to a separate earnings process and are deemed to be substantive and at risk, revenue is recognized when such milestones are achieved. In addition, the Company recognizes research and development support revenue from certain collaboration and development agreements based upon the level of research services performed during the period of the relevant research agreement. Deferred revenue substantially represents amounts received under collaborative agreements and not yet earned pursuant to these policies. Where the Company has no continuing involvement, the Company will record non-refundable license fees as revenue upon receipt and will record revenue upon achievement of milestones by its collaborative partners.

The Company produces preclinical and clinical materials for its collaborators. The Company is reimbursed for certain of its direct and overhead costs to produce clinical materials. The Company recognizes revenue on preclinical and clinical materials when the materials have passed all quality testing required for collaborator acceptance and title and risk of loss have transferred to the collaborator.

The Company also produces research material for potential collaborators under material transfer agreements. Additionally, the Company performs research activities, including developing antibody-specific conjugation processes, on behalf of its collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. Generally, the Company is reimbursed for certain of its direct and overhead costs of producing these materials or providing these services. The Company records the amounts received for the preclinical materials produced or services performed as a component of research and development support. The Company also develops conjugation processes for materials for later stage testing and commercialization for certain

Table of Contents

collaborators. The Company is reimbursed for its direct and overhead costs and may receive milestone payments for developing these processes and these are recorded as a component of research and development support.

*Marketable Securities*

The Company invests in marketable securities of highly rated financial institutions and investment-grade debt instruments and limits the amount of credit exposure with any one entity. The Company has classified its marketable securities as available-for-sale and, accordingly, carries such securities at aggregate fair value. Unrealized gains and losses, if any, are reported as other comprehensive income (loss) in shareholders' equity. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretions are included in other income, net, as well as interest and dividends. Realized gains and losses on available-for-sale securities are also included in other income, net, as well as charges for the impairment of available-for-sale securities that were determined to be other-than-temporary due to a decline in value. The cost of securities sold is based on the specific identification method. In December 2007, the Company was notified by a fund manager that a fund in which the Company held an \$18.2 million investment was unable to meet shareholder redemptions on a timely basis. The Company held approximately \$4.7 million in this fund at December 31, 2008. Although amounts invested are not currently impaired in value, the balance is not readily convertible to cash. The Company has the option of redeeming the entire investment from the fund in-kind which would consist of individual securities, or remaining in the fund and receiving cash redemptions as cash becomes available in the fund either through maturities or sales of the underlying securities. The Company opted to stay in the fund and has received \$13.8 million in redemptions, all at par, since December 2007. In December 2007, the Company reclassified the balance in this fund from cash and cash equivalents to marketable securities. The Company expects to receive at least \$3.3 million in redemptions during the remainder of fiscal 2009 and the balance in subsequent periods.

*Fair Value of Financial Instruments*

As of July 1, 2008, the Company partially adopted the provisions of FASB Statement No. 157, *Fair Value Measurements*, or Statement 157, for financial assets and liabilities recognized at fair value on a recurring basis. Statement 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the U.S., and expands disclosures about fair value measurements. The provisions of Statement 157 related to other non-financial assets and liabilities will be effective for the Company on July 1, 2009, and will be applied prospectively.

Fair value is defined under Statement 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under Statement 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy to measure fair value which is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be

corroborated by observable market data for substantially the full term of the assets or liabilities.

- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of December 31, 2008, we held certain assets that are required to be measured at fair value on a recurring basis, including our cash equivalents and marketable securities. In accordance with Statement 157, the following table represents the fair value hierarchy for our financial assets measured at fair value on a recurring basis as of December 31, 2008 (in thousands):

	Total	Fair Value Measurements at December 31, 2008 Using		Significant Unobservable Inputs (Level 3)
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	
Cash, cash equivalents and restricted cash	\$ 42,252	\$ 42,252	\$	\$
Available-for-sale marketable securities	8,485		8,485	
	\$ 50,737	\$ 42,252	\$ 8,485	\$

The fair value of the Company's investments is generally determined from market prices based upon either quoted prices from active markets or other significant observable market transactions at fair value.

Investments are considered to be impaired when a decline in fair value below cost basis is determined to be other-than-temporary.

Table of Contents

The Company periodically evaluates whether a decline in fair value below cost basis is other-than-temporary and considers available evidence regarding the investments. In the event that the cost basis of a security significantly exceeds its fair value, the Company evaluates, among other factors, the duration of the period that, and extent to which, the fair value is less than cost basis; the financial health of and business outlook for the issuer, including industry and sector performance, operational and financing cash flow factors, overall market conditions and trends, and our intent and ability to hold the investment to recovery, which may be maturity. The Company also considers credit ratings with respect to our investments provided by investment rating agencies. All of the Company's investments are classified as available-for-sale securities and are reflected at fair value. If a decline in fair value is determined to be other-than-temporary, the Company records a write-down in its consolidated statement of operations and a new cost basis in the security is established. During the three and six months ended December 31, 2008, the Company recorded \$266,000 and \$402,000, respectively as other-than-temporary impairment charges. No such charges were recorded during the three and six months ended December 31, 2007.

*Unbilled Revenue*

The majority of the Company's unbilled revenue at December 31, 2008 and June 30, 2008 represents (i) research funding earned based on actual resources utilized under the Company's discovery, development and commercialization agreement with sanofi-aventis; (ii) reimbursable expenses incurred under the Company's discovery, development and commercialization agreement with sanofi-aventis and license agreement with Biotest that the Company has not yet invoiced; and (iii) research funding earned based on actual resources utilized under the Company's development, license and service agreements with Bayer Healthcare, Biogen Idec and Biotest.

*Inventory*

Inventory costs primarily relate to clinical trial materials being manufactured for sale to the Company's collaborators. Inventory is stated at the lower of cost or market as determined on a first-in, first-out (FIFO) basis.

Inventory at December 31, 2008 and June 30, 2008 is summarized below (in thousands):

	<b>December 31, 2008</b>	<b>June 30, 2008</b>
Raw materials	\$ 480	\$ 565
Work in process		1,551
Total	\$ 480	\$ 2,116

All Tumor-Activated Prodrug, or TAP, product candidates currently in preclinical and clinical testing through ImmunoGen or its collaborators include either DM1 or DM4 as a cell-killing agent. Raw materials inventory consists entirely of DM1 and DM4, collectively referred to as DMx.

## Edgar Filing: IMMUNOGEN INC - Form 10-Q

Inventory cost is stated net of write-downs of \$2.5 million as of December 31, 2008 and June 30, 2008. The write-downs represent the cost of raw materials that the Company considers to be in excess of a twelve-month supply based on firm, fixed orders and projections from its collaborators as of the respective balance sheet date.

The Company produces preclinical and clinical materials for its collaborators either in anticipation of or in support of preclinical studies and clinical trials, or for process development and analytical purposes. Under the terms of supply agreements with its collaborators, the Company generally receives rolling six-month firm, fixed orders for conjugate that the Company is required to manufacture, and rolling twelve-month manufacturing projections for the quantity of conjugate the collaborator expects to need in the related twelve-month period. The amount of clinical material produced is directly related to the number of Company and collaborator anticipated or on-going clinical trials for which the Company is producing clinical material, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period, if any, during which patients in the trial receive clinical benefit from the clinical materials. Because these elements are difficult to estimate over the course of a trial, substantial differences between collaborators' actual manufacturing orders and their projections could result in usage of raw materials varying significantly from estimated usage at an earlier reporting period. To the extent that a collaborator has provided the Company with a firm, fixed order, the collaborator is required by contract to reimburse the Company the full cost of the conjugate and any agreed margin thereon, even if the collaborator subsequently cancels the manufacturing run.

The Company accounts for the raw material inventory as follows:

- a) raw material is capitalized as inventory upon receipt of the materials. That portion of the raw material the Company uses in



Table of Contents

the production of its own products is recorded as research and development expense as consumed;

b) to the extent that the Company has up to twelve months of firm, fixed orders and/or projections from its collaborators, the Company capitalizes the value of raw materials that will be used in the production of conjugate subject to these firm, fixed orders and/or projections;

c) the Company considers more than a twelve month supply of raw materials that is not supported by firm, fixed orders or projections from its collaborators to be excess and establishes a reserve to reduce to zero the value of any such excess raw material inventory with a corresponding charge to research and development expense; and

d) the Company also considers any other external factors and information of which it becomes aware and assesses the impact of such factors or information on the net realizable value of the raw material inventory at each reporting period.

The Company did not record any expense related to excess inventory during the six month periods ended December 31, 2008 and 2007. Increases in the Company's on-hand supply of raw materials, or a reduction to the Company's collaborators' projections, could result in significant changes in the Company's estimate of the net realizable value of such raw material inventory. Reductions in collaborators' projections could indicate that the Company has additional excess raw material inventory and the Company would then evaluate the need to record further write-downs as charges to research and development expense.

*Computation of Net Loss per Common Share*

Basic and diluted net loss per share is calculated based upon the weighted average number of common shares outstanding during the period. The Company's common stock equivalents, as calculated in accordance with the treasury-stock accounting method, are shown in the following table (in thousands):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2008	2007	2008	2007
Options to purchase common stock	5,629	4,889	5,629	4,889
Common stock equivalents under treasury stock method	312	462	516	483

The Company's common stock equivalents have not been included in the net loss per share calculation because their effect is anti-dilutive due to the Company's net loss position.

*Comprehensive Loss*

The Company presents comprehensive loss in accordance with FASB Statement No. 130, *Reporting Comprehensive Income*. For the three and six months ended December 31, 2008, total comprehensive loss equaled \$7.3 million and \$16.6 million, respectively. For the three and six months ended December 31, 2007, total comprehensive loss equaled \$6.3 million and \$7.3 million respectively. Comprehensive loss is comprised of the Company's net loss for the period and unrealized gains and losses recognized on available-for-sale marketable securities.

*Stock-Based Compensation*

As of December 31, 2008, the Company is authorized to grant future awards under one employee share-based compensation plan, which is the ImmunoGen, Inc. 2006 Employee, Director and Consultant Equity Incentive Plan, or the 2006 Plan. The 2006 Plan was approved by the Company's Board of Directors and the shareholders of the Company on November 14, 2006 and replaced the previous stock option plan, the ImmunoGen, Inc. Restated Stock Option Plan, as amended, or the Former Plan. At the annual meeting of shareholders on November 12, 2008, an amendment to the 2006 Plan was approved and an additional 2,000,000 shares were authorized for issuance under this plan. As amended, the 2006 Plan provides for the issuance of Stock Grants, the grant of Options and the grant of Stock-Based Awards for up to 4,500,000 shares of the Company's common stock, as well as any shares of common stock that are represented by awards granted under the Former Plan that are forfeited, expire or are cancelled without delivery of shares of common stock or which result in the forfeiture of shares of common stock back to the Company on or after November 13, 2006, or the equivalent of such number of shares after the Administrator, in its sole discretion, has interpreted the effect of any stock split, stock dividend, combination, recapitalization or similar transaction in accordance with the 2006 Plan; provided, however, that no more than 5,900,000 shares shall be added to the Plan from the Former Plan, pursuant to this provision. Option awards are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Options vest at various periods of up to four years and may be exercised within ten years of the date of grant.

Table of Contents

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model with the assumptions noted in the following table. As the Company has not paid dividends since inception, nor does it expect to pay any dividends for the foreseeable future, the expected dividend yield assumption is zero. Expected volatility is based exclusively on historical volatility data of the Company's stock. The expected term of stock options granted is based exclusively on historical data and represents the period of time that stock options granted are expected to be outstanding. The expected term is calculated for and applied to one group of stock options as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. The risk-free rate of the stock options is based on the U.S. Treasury rate in effect at the time of grant for the expected term of the stock options.

	Three Months Ended December 31,		Six Months Ended December 31,	
	2008	2007	2008	2007
Dividend	None	None	None	None
Volatility	63.39%	75.82%	63.33%	75.49%
Risk-free interest rate	3.11%	3.85%	3.14%	3.91%
Expected life (years)	7.1	7.5	7.1	7.4

Using the Black-Scholes option-pricing model, the weighted average grant date fair values of options granted during the three months ended December 31, 2008 and 2007 were \$2.65 and \$3.50 per share, respectively, and \$2.71 and \$3.50 for options granted during the six months ended December 31, 2008 and 2007, respectively.

Compensation cost incurred during the three and six months ended December 31, 2008 was \$838,000 and \$2.1 million respectively. Compensation cost incurred during the three and six months ended December 31, 2007 was \$546,000 and \$1.1 million respectively. During the three and six months ended December 31, 2008 we recorded approximately \$35,000 and \$747,000, respectively, of compensation expense, which is included in the amounts above, related to the modification of the terms certain of options previously granted to the Chief Executive Officer of the Company in accordance with the succession plan approved by our Board of Directors in September 2008.

As of December 31, 2008, the estimated fair value of unvested employee awards was \$3.7 million, net of estimated forfeitures. The weighted-average remaining vesting period for these awards is approximately two and a half years.

During the six months ended December 31, 2008, holders of options issued under the Plan exercised their rights to acquire an aggregate of 109,000 shares of common stock at prices ranging from \$1.38 to \$5.34 per share. The total proceeds to the Company from these option exercises were approximately \$268,000.

*Derivatives*

Derivative instruments include a portfolio of short duration foreign currency forward contracts intended to mitigate the risk of exchange fluctuations for existing or anticipated receivable and payable balances denominated in foreign currency. Derivatives are estimated at fair value and classified as other current assets or liabilities. The fair value of these instruments represent the present value of estimated future cash flows under the contracts, which are a function of underlying interest rates, currency rates, related volatility, counterparty creditworthiness and duration of the contracts. Changes in these factors or a combination thereof may affect the fair value of these instruments.

The Company does not designate foreign currency forward contracts as hedges for accounting purposes, and changes in the fair value of these instruments are recognized in earnings during the period of change. Because the Company enters into forward contracts only as an economic hedge, any gain or loss on the underlying foreign-denominated existing or anticipated receivable or payable balance would be offset by the loss or gain on the forward contract. For the three and six months ended December 31, 2008, net losses recognized on forward contracts were \$79,000 and \$182,000, respectively, and are included in the accompanying consolidated statement of operations as other (loss) income, net. As of December 31, 2008, the Company had outstanding forward contracts with amounts equivalent to approximately \$3.4 million (2.6 million in Euros), all maturing on or before February 27, 2009. As of June 30, 2008, the Company had outstanding forward contracts with amounts equivalent to approximately \$1.4 million (924,000 in Euros). For the three and six months ended December 31, 2007, net gains recognized on forward contracts were \$49,000 and \$242,000, respectively. As of December 31, 2007, the Company had outstanding forward contracts with amounts equivalent to approximately \$7.4 million (5.1 million in Euros). The Company does not anticipate using derivative instruments for any purpose other than hedging our exchange rate exposure.

*Segment Information*

During the three and six months ended December 31, 2008, the Company continued to operate in one reportable business segment under the management approach of FASB Statement No. 131, *Disclosures about Segments of an Enterprise and Related Information*, which is the business of discovery of monoclonal antibody-based anticancer therapeutics.

Table of Contents

The percentages of revenues recognized from significant customers of the Company in the three and six months ended December 31, 2008 and 2007 are included in the following table:

Collaborative Partner:	Three Months Ended December 31,		Six Months Ended December 31,	
	2008	2007	2008	2007
sanofi-aventis	80%	58%	68%	51%
Genentech	1%	16%	1%	32%
Biogen Idec	2%	13%	7%	6%
Biotest	13%	12%	15%	8%

There were no other customers of the Company with significant revenues in the three or six months ended December 31, 2008 and 2007.

## B. Significant Collaborative Agreements

### *sanofi-aventis*

In August 2006, sanofi-aventis exercised its final remaining option to extend the term of the research collaboration with the Company for another year, and committed to pay the Company a minimum of \$10.4 million in research support over the twelve months beginning September 1, 2007. The two companies subsequently agreed to extend the date of payment through October 31, 2008 to enable completion of previously agreed upon research. The Company records the research funding as it is earned based upon its actual resources utilized in the collaboration. Through the end of the research program, the Company has earned \$81.5 million of committed funding. As with all of its collaborative partners, the Company now performs research for sanofi-aventis and receives financial compensation from them on a mutually-agreed upon basis.

In October 2006, sanofi-aventis licensed non-exclusive rights to use the Company's proprietary resurfacing technology to humanize antibodies to targets not included in the collaboration, including antibodies for non-cancer applications. This license provides sanofi-aventis with the non-exclusive right to use the Company's proprietary humanization technology through August 31, 2011 with the right to extend for one or more additional periods of three years each by providing the Company with written notice prior to expiration of the then-current license term and payment of a specified renewal fee. Under the terms of the license, the Company received a \$1 million license fee, half of which was paid upon contract signing and the second half was paid in August 2008, and in addition, the Company is entitled to receive milestone payments potentially totaling \$4.5 million for each licensed product under this agreement and also royalties on commercial sales, if any. The Company has deferred the \$1 million upfront payment and is recognizing this amount as revenue over the five-year term of the agreement.

In August 2008, sanofi-aventis exercised its option under a 2006 agreement for expanded access to the Company's TAP technology. The exercise of this option enables sanofi-aventis to evaluate, with certain restrictions, the Company's maytansinoid TAP technology with antibodies to targets not licensed as part of the research collaboration between the companies and to take licenses for the exclusive right to use the technology to develop products to specific targets on the terms in the 2006 agreement. The Company is entitled to earn upfront and milestone payments potentially totaling \$32 million per target for each compound developed under the 2006 agreement, as well as royalties on commercial sales. The Company is also entitled to manufacturing payments for any materials made on behalf of sanofi-aventis. The Company received \$3.5 million with the exercise of this option in August 2008, in addition to the \$500,000 the Company received in December 2006 with the signing of the

## Edgar Filing: IMMUNOGEN INC - Form 10-Q

option agreement. The agreement has a three-year term from the date of the exercise of the option and can be renewed by sanofi-aventis for one additional three-year term by payment of a \$2 million fee. The Company has deferred the \$3.5 million exercise fee and is recognizing this amount as revenue over the initial three-year option term.

In October 2008, sanofi-aventis began Phase II evaluation of AVE1642, triggering a \$4 million milestone payment to the Company. This milestone is included in license and milestone fee revenue for the three and six months ended December 31, 2008.

*Genentech, Inc.*

## Edgar Filing: IMMUNOGEN INC - Form 10-Q

Genentech began Phase II evaluation of trastuzumab-DM1, or T-DM1, in July 2007 and the Company received a \$5 million milestone payment with this event. Of the \$5 million milestone payment received, \$3 million is included in license and milestone fees for the three months ended December 31, 2007. The balance of the \$5 million milestone was earned during the third quarter of fiscal 2008. The milestone was earned under the May 2000 license agreement, as amended in 2006. This amendment increased the potential milestone payments to the Company in conjunction with the achievement of milestones earned under a separate process development agreement with Genentech.

In December 2008, Genentech licensed the exclusive right to use the Company's maytansinoid TAP technology with its

Table of Contents

therapeutic antibodies to an undisclosed target. This license was taken under an agreement entered into by the companies in 2000 that provided Genentech with the right to take exclusive licenses to use the Company's maytansinoid TAP technology to develop products for individual targets on agreed upon terms. Under the terms of the license, the Company received a \$1 million upfront payment and is entitled to receive milestone payments plus royalties on the sales of any resulting products. Genentech is responsible for the development, manufacturing, and marketing of any products resulting from this license. The Company has deferred the \$1 million upfront payment and is recognizing this amount as revenue over the estimated period of substantial involvement.

*Bayer HealthCare AG*

In October 2008, the Company entered into a development and license agreement with Bayer HealthCare AG. The agreement grants Bayer exclusive rights to use the Company's TAP technology to develop therapeutic compounds to a target found on solid tumors. The Company received a \$4 million upfront payment upon execution of the agreement, and for each compound developed and marketed by Bayer under this collaboration the Company could potentially receive up to \$170.5 million in milestone payments; additionally, the Company receives royalties on the sales of any resulting products. The Company will be compensated by Bayer at a stipulated rate for work performed on behalf of Bayer under a mutually agreed upon research plan and budget which may be amended from time to time during the term of the agreement. The Company also will receive payments for manufacturing any preclinical and clinical materials made at the request of Bayer, and for any related process development activities. The Company has deferred the \$4 million upfront payment and is recognizing this amount as revenue over the estimated period of substantial involvement.

The Company has agreements with other companies with respect to its compounds, as described elsewhere in this Quarterly Report and in its 2008 Annual Report on Form 10-K.

**C. Capital Stock**

*2001 Non-Employee Director Stock Plan*

During the three and six months ended December 31, 2008, the Company recorded approximately \$(9,000) and \$19,000 in (expense reduction) or compensation expense, respectively, related to stock units outstanding under the Company's 2001 Non-Employee Director Stock Plan. The value of the stock units is adjusted to market value at each reporting period as the redemption amount of stock units for this plan will be paid in cash. No stock units have been issued under the 2001 Plan subsequent to June 30, 2004. During the three and six months ended December 31, 2007, the Company recorded approximately \$(8,000) and \$(21,000) in expense reduction, respectively.

*2004 Non-Employee Director Compensation and Deferred Share Unit Plan*

The 2004 Non-Employee Director Compensation and Deferred Share Unit Plan, or 2004 Director Plan, was amended on September 5, 2006. Under the terms of the amended 2004 Director Plan, the redemption amount of deferred share units will be paid in shares of common stock of the Company. In addition, the vesting for annual retainers is to take place quarterly over the three years after the award and the number of



deferred share units awarded for all compensation is now based on the market value of the Company's common stock on the date of the award.

During the three and six months ended December 31, 2008, the Company recorded approximately \$37,000 and \$71,000 in compensation expense, respectively, related to deferred share units outstanding under the amended 2004 Director Plan. During the three and six months ended December 31, 2007, the Company recorded approximately \$16,000 and \$23,000 in compensation expense, respectively.

#### **D. Commitments and Contingencies**

Effective July 27, 2007, the Company entered into a lease agreement with Intercontinental Fund III for the rental of approximately 89,000 square feet of laboratory and office space at 830 Winter Street, Waltham, MA. The Company occupied the space on March 24, 2008 and uses this space for its corporate headquarters, research and other operations previously located in Cambridge, MA. The initial term of the lease is for twelve years with an option for the Company to extend the lease for two additional terms of five years. The Company is required to pay certain operating expenses for the leased premises subject to escalation charges for certain expense increases over a base amount.

As part of the lease agreement, the Company received a construction allowance of up to approximately \$13.3 million to build out laboratory and office space to the Company's specifications. The construction allowance is accounted for as a lease incentive pursuant to FASB Statement No. 13, *Accounting for Leases*, and FASB Technical Bulletin 88-1, *Issues Relating to Accounting for Leases*. After completion, the Company had recorded \$12 million of leasehold improvements under the construction allowance. The Company received \$10.8 million from the landlord and paid out the same amount towards these leasehold improvements. The remaining balance of the improvements was paid directly by the landlord. The lease term began on October 1, 2007, when the Company obtained physical control of the space in order to begin construction.

Under the terms of the agreement, the remaining \$1.3 million of the construction allowance is to be applied evenly as a

Table of Contents

credit to rent for the first year. The final balance of the construction allowance was determined in August 2008, resulting in a credit of \$1 million to the Company from the landlord during the current six-month period relating to the first nine months of occupancy. The balance of the credit will be applied evenly to the remaining three months of the first year of rent.

At December 31, 2008, the Company also leases facilities in Norwood and Cambridge, MA under agreements through 2011. The Company is required to pay certain operating expenses for the leased premises subject to escalation charges for certain expense increases over a base amount. The Company entered into a sub-sublease in May 2008 for the entire space in Cambridge, MA through 2011, the remainder of the sublease.

The minimum rental commitments, including real estate taxes and other expenses, for the next five fiscal years under the non-cancelable operating lease agreements discussed above are as follows (in thousands):

2009 (six months remaining)	\$	2,660
2010		6,108
2011		5,671
2012		4,646
2013		4,646
Total minimum lease payments	\$	23,731
Total minimum rental income from sub-sublease		(1,446)
Total minimum lease payments, net	\$	22,285

The Company intends to sublease approximately 14,000 rentable square feet of laboratory and office space at 830 Winter Street, Waltham, MA. The Company has not included any estimated sublease income for the space in Waltham in the table above.

**E. Income Taxes**

During the three and six months ended December 31, 2008, the Company recognized approximately \$101,000 of tax benefit associated with U.S. research and development tax credits against which the Company had previously provided a full valuation allowance, but which became refundable as a result of legislation passed in July 2008. There were no other significant income tax provisions or benefits for the six months ended December 31, 2008. Due to the degree of uncertainty related to the ultimate use of loss carryforwards and tax credits, the Company has established a valuation allowance to fully reserve the remaining tax benefits.

**ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

**OVERVIEW**

Since our inception, we have been principally engaged in the development of novel, targeted therapeutics for the treatment of cancer using our expertise in cancer biology, monoclonal antibodies, and small-molecule cytotoxic, or cell-killing, agents. Our Tumor-Activated Prodrug, or TAP, technology uses antibodies to deliver a potent cytotoxic agent specifically to cancer targets, and consists of a monoclonal antibody that binds to a cancer target with one of our proprietary cell-killing agents attached. The antibody component enables a TAP compound to bind specifically to cancer cells that express a particular target antigen and the cytotoxic agent serves to kill the cancer cell. Our TAP technology is designed to enable the creation of highly effective, well-tolerated anticancer products. All of our and our collaborative partners' TAP compounds currently in preclinical and clinical testing contain either DM1 or DM4 as the cytotoxic agent. Both DM1 and DM4 are our proprietary derivatives of a naturally occurring substance called maytansine. We also use our expertise in antibodies and cancer biology to develop naked, or unconjugated, antibody anticancer product candidates.

We have entered into collaborative agreements that enable companies to use our TAP technology to develop commercial product candidates to specified targets. We have also used our proprietary TAP technology in conjunction with our in-house antibody expertise to develop our own anticancer product candidates. Under the terms of our collaborative agreements, we are generally entitled to upfront fees, milestone payments and royalties on any commercial product sales. In addition, under certain agreements we are entitled to research and development funding based on activities performed at our collaborative partner's request. We are reimbursed our direct and overhead costs to manufacture preclinical and clinical materials and, under certain collaborative agreements, the reimbursement includes a profit margin. Currently, our collaborative partners include Amgen, Inc., Bayer HealthCare AG, Biogen Idec Inc., Biotest AG, Genentech, Inc., and sanofi-aventis. We expect that substantially all of our revenue for the foreseeable future will result from payments under our collaborative arrangements.

*sanofi-aventis* In July 2003, we entered into a discovery, development and commercialization collaboration with sanofi-aventis. Under the terms of this agreement, in consideration of an upfront payment of \$12 million, sanofi-aventis gained commercialization rights to new anticancer therapeutics developed to targets included in the collaboration, including the right to use our TAP technology and our humanization technology in the creation of therapeutics to these targets. The agreement included a

Table of Contents

research support funding commitment by sanofi-aventis for \$50.7 million over the first three years of the agreement, and then for an additional \$18.2 million when the agreement was extended for a fourth year, and then for an additional \$10.4 million when the agreement was extended for a fifth year. The two companies subsequently agreed to extend the date of payment through October 31, 2008 to enable completion of previously agreed upon research. We have earned \$81.5 million of committed research funding for activities performed under the completed research term of this agreement. As with all of its collaborative partners, we now perform research for sanofi-aventis and receive financial compensation from them on a mutually-agreed upon basis..

The collaboration agreement also provides for certain other payments based on the achievement of product candidate milestones and royalties on sales of any resulting products, if and when such sales commence. Assuming all benchmarks are met, we will receive payments of between \$21.5 million and \$30 million per antigen target for each product candidate developed under this agreement. Through December 31, 2008, we have received and earned \$10.5 million with the achievement of various milestones related to five of the targets in this collaboration that have been disclosed.

Additionally, in October 2006, sanofi-aventis licensed non-exclusive rights to use our proprietary humanization technology, which enables antibodies of murine origin to avoid detection by the human immune system. This license provides sanofi-aventis with the non-exclusive right to use our proprietary humanization technology through August 31, 2011 with the right to extend for one or more additional periods of three years each by providing us with written notice prior to expiration of the then-current license term and payment of a specified renewal fee. Under the terms of the license, we received a \$1 million license fee, half of which was paid upon contract signing and the second half was paid in August 2008, and in addition, we are entitled to receive milestone payments potentially totaling \$4.5 million plus royalties on sales for each licensed product under this agreement. We have deferred the \$1 million upfront payment and are recognizing this amount as revenue over the five-year term of the agreement.

In August 2008, sanofi-aventis exercised its option under a 2006 agreement for expanded access to our TAP technology. The exercise of this option enables sanofi-aventis to evaluate, with certain restrictions, our maytansinoid TAP technology with antibodies to targets not licensed as part of the research collaboration between the companies and to take licenses for the exclusive right to use the technology to develop products to specific targets on the terms in the 2006 agreement. We are entitled to earn upfront and milestone payments potentially totaling \$32 million per target for each compound developed under the 2006 agreement, as well as royalties on commercial sales. We are also entitled to manufacturing payments for any materials made on behalf of sanofi-aventis. We received \$3.5 million with the exercise of this option in August 2008, in addition to the \$500,000 we received in December 2006 with the signing of the option agreement. The agreement has a three-year term from the date of the exercise of the option and can be renewed by sanofi-aventis for one additional three-year term by payment of a \$2 million fee. We have deferred the \$3.5 million exercise fee and are recognizing this amount as revenue over the initial three-year option term.

In October 2008, sanofi-aventis began Phase II evaluation of AVE1642, triggering a \$4 million milestone payment to us. This milestone is included in license and milestone fee revenue for the three and six months ended December 31, 2008.

*Genentech* In May 2000, we entered into a license agreement with Genentech that granted Genentech exclusive rights to use our maytansinoid TAP technology with antibodies that target HER2. We received a \$2 million upfront payment upon execution of the agreement. In addition to royalties on net sales of any HER2-targeting TAP compounds developed under this agreement if and when they occur, the terms of the agreement include other payments based upon Genentech's achievement of milestones. In May 2006, we amended this agreement which increased the potential milestone payments and certain royalties. Assuming all requirements are met under this agreement, we are to receive \$44 million in milestone payments under this agreement in addition to royalties on sales, if any. Through

December 31, 2008, we have received \$7 million in milestone payments.

In December 2008, Genentech licensed the exclusive right to use our maytansinoid TAP technology with its therapeutic antibodies to an undisclosed target. This license was taken under an agreement entered into by the companies in 2000 that provided Genentech with the right to take exclusive licenses to use our maytansinoid TAP technology to develop products for individual targets on agreed upon terms. Under the terms of the license, we received a \$1 million upfront payment and are entitled to receive milestone payments plus royalties on the sales of any resulting products. Genentech is responsible for the development, manufacturing, and marketing of any products resulting from this license. We have deferred the \$1 million upfront payment and are recognizing this amount as revenue over the estimated period of substantial involvement.

*Biotest AG* In September 2008, Biotest began Phase I evaluation of BT-062 which triggered a \$500,000 milestone payment to us. This milestone is included in license and milestone fee revenue for the six months ended December 31, 2008.

*Bayer HealthCare AG* In October 2008, we entered into a development and license agreement with Bayer HealthCare AG. The agreement grants Bayer exclusive rights to use our TAP technology to develop therapeutic compounds to a target found on solid tumors. We received a \$4 million upfront payment upon execution of the agreement, and for each compound developed and marketed by Bayer under this collaboration we could potentially receive up to \$170.5 million in milestone payments; additionally, we receive royalties on the sales of any resulting products. We will be compensated by Bayer at a stipulated rate for work performed on behalf of Bayer under a mutually agreed upon research plan and budget which may be amended from time to time during the term of the agreement. We also will receive payments for manufacturing any preclinical and clinical materials made at the request of Bayer as well as for any related process development activities. We have deferred the \$4 million upfront payment and are recognizing this

Table of Contents

amount as revenue over the estimated period of substantial involvement.

To date, we have not generated revenues from commercial product sales and we expect to incur significant operating losses for the foreseeable future. As of December 31, 2008, we had approximately \$45.9 million in cash and marketable securities compared to \$47.9 million in cash and marketable securities as of June 30, 2008.

We anticipate that future cash expenditures will be partially offset by collaboration-derived proceeds, including milestone payments, clinical material reimbursements and upfront fees. Accordingly, period-to-period operational results may fluctuate dramatically based upon the timing of receipt of the proceeds. We believe that our established collaborative agreements, while subject to specified milestone achievements, will provide funding to assist us in meeting obligations under our collaborative agreements while also assisting in providing funding for the development of internal product candidates and technologies. However, we can give no assurances that such collaborative agreement funding will, in fact, be realized in the time frames we expect, or at all. Should we or our partners not meet some or all of the terms and conditions of our various collaboration agreements, we may be required to pursue additional strategic partners, secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects. However, we cannot provide assurance that any such opportunities presented by additional strategic partners or alternative financing arrangements will be entirely available to us, if at all.

*Critical Accounting Policies*

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to our collaborative agreements and inventory. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

*Revenue Recognition*

We enter into licensing and development agreements with collaborative partners for the development of monoclonal antibody-based anticancer therapeutics. We follow the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin No. 104, *Revenue Recognition*, or SAB 104, and Emerging Issues Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Elements*, or EITF 00-21. In accordance with SAB 104 and EITF 00-21, we recognize revenue related to research activities as they are performed, as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is probable. The terms of our agreements contain multiple elements which typically include non-refundable license fees, payments based upon the achievement of certain milestones and royalties on product sales. We evaluate such arrangements to determine if the deliverables are separable into units of accounting and then apply applicable revenue recognition criteria to each unit of accounting.

## Edgar Filing: IMMUNOGEN INC - Form 10-Q

At December 31, 2008, we had the following three types of collaborative contracts with the parties identified below:

- License to use our TAP technology and/or certain other intellectual property to develop compounds to a single target antigen:

Biogen Idec Inc. (single-target license)

Biotest AG (single-target license)

Genentech, Inc. (multiple single-target licenses)

sanofi-aventis (license to multiple individual targets)

Bayer Healthcare AG (single-target license)

- Option agreement for a defined period of time to secure licenses to use our TAP technology to develop anticancer compounds to a limited number of targets on established terms (broad option agreement):

Amgen, Inc.

Genentech, Inc.

sanofi-aventis

- Non-exclusive license to our humanization technology:

sanofi-aventis

Generally, the foregoing collaboration agreements provide that we will (i) at the collaborator's request, manufacture preclinical and clinical materials at our cost, or, in some cases, cost plus a margin, (ii) earn payments upon the collaborators' achievements of certain milestones and (iii) earn royalty payments, generally until the later of the last applicable patent expiration or twelve years after product launch. Royalty rates may vary over the royalty term depending on certain intellectual property rights. We are required to

Table of Contents

provide technical training and to share any process improvements and know-how with its collaborators during the research term of the collaboration agreements.

Generally, upfront payments on single-target licenses are deferred over the period of our substantial involvement during development. The determination of the length of this period is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period. Our employees are available to assist the Company's collaborators during the development of their products. We estimate this development phase to begin at the inception of the collaboration agreement and conclude at the end of non-pivotal Phase II testing. We believe this period of involvement is, depending on the nature of the license, on average six and one-half years. Quarterly, we reassess our periods of substantial involvement over which we amortize our upfront license fees. In the event that a single-target license were to be terminated, we would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue at the date of such termination.

We defer upfront payments received from our broad option agreements over the period during which the collaborator may elect to receive a license. These periods are specific to each collaboration agreement, but are between seven and 12 years. If a collaborator selects an option to acquire a license under these agreements, any option fee is deferred and recorded over the life of the option, generally 12 to 18 months. If a collaborator exercises an option and we grant a single-target license to the collaborator, we defer the license fee and account for the fee as we would an upfront payment on a single-target license, as discussed above. Upon exercise of an option to acquire a license, we would recognize any remaining deferred option fee over the period of our substantial involvement under the license acquired. In the event a broad option agreement were to be terminated, we would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue at the date of such termination. In the event a collaborator elects to discontinue development of a specific product candidate under a single-target license, but retains its right to use our technology to develop an alternative product candidate to the same target or a target substitute, we would cease amortization of any remaining portion of the upfront fee until there is substantial preclinical activity on another product candidate and our remaining period of substantial involvement can be estimated.

When milestone fees are specifically tied to a separate earnings process and are deemed to be substantive and at risk, revenue is recognized when such milestones are achieved. In addition, we recognize research and development support revenue from certain collaboration and development agreements based upon the level of research services performed during the period of the research agreement. Deferred revenue substantially represents amounts received under collaborative agreements and not yet earned pursuant to these policies. Where we have no continuing involvement, we will record non-refundable license fees as revenue upon receipt and will record revenue upon achievement of milestones by its collaborative partners.

We produce preclinical and clinical materials for our collaborators. We are reimbursed for certain of our direct and overhead costs to produce clinical materials. We recognize revenue on preclinical and clinical materials when the materials have passed all quality testing required for collaborator acceptance and title and risk of loss have transferred to the collaborator.

We also produce research material for potential collaborators under material transfer agreements. Additionally, we perform research activities, including developing antibody-specific conjugation processes, on behalf of our collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. Generally, we are reimbursed for certain of our direct and overhead costs of producing these materials or providing these services. We record the amounts received for the materials produced or services performed as a component of research and development support. We also develop conjugation processes for materials for later stage testing and commercialization for certain collaborators. We are reimbursed for certain of our direct and overhead costs and may receive milestone payments for developing these processes and these are recorded as a component of research and development support.



*Inventory*

We review our estimates of the net realizable value of our inventory at each reporting period. Our estimate of the net realizable value of our inventory is subject to judgment and estimation. The actual net realizable value of our inventory could vary significantly from our estimates. We consider quantities of raw materials in excess of twelve-month projected usage that is not supported by firm, fixed collaborator orders and projections at the time of the assessment to be excess. To date, we have fully reserved any such material identified as excess with a corresponding charge to research and development expense. Our collaborators' estimates of their clinical material requirements are based upon expectations of their clinical trials, including the timing, size, dosing schedule and the maximum tolerated dose likely to be reached for the compound being evaluated. Our collaborators' actual requirements for clinical materials may vary significantly from their projections. Significant differences between our collaborators' actual manufacturing orders and their projections could result in our actual twelve-month usage of raw materials varying significantly from our estimated usage at an earlier reporting period. Reductions in collaborators' projections could indicate that we have additional excess raw material inventory and we would then evaluate the need to record further write-downs, which would be included as charges to research and development expense.

*Stock Based Compensation*

As of December 31, 2008, the Company is authorized to grant future awards under one share-based compensation plan, which is the ImmunoGen, Inc. 2006 Employee, Director and Consultant Equity Incentive Plan. Effective July 1, 2005, we adopted the fair

Table of Contents

value recognition provisions of Financial Accounting Standards Board, or FASB, Statement No. 123(R), *Share-Based Payment*, or Statement 123(R), using the modified-prospective-transition method. Under that transition method, compensation cost includes: (a) compensation cost for all share-based payments granted, but not yet vested as of July 1, 2005, based on the grant-date fair value estimated in accordance with the original provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, or Statement 123, and (b) compensation cost for all share-based payments granted subsequent to July 1, 2005, based on the grant-date fair value estimated in accordance with the provisions of Statement 123(R). Such amounts have been reduced by our estimate of forfeitures of all unvested awards.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model. Expected volatility is based exclusively on historical volatility data of our stock. The expected term of stock options granted is based exclusively on historical data and represents the period of time that stock options granted are expected to be outstanding. The expected term is calculated for and applied to one group of stock options as we do not expect substantially different exercise or post-vesting termination behavior amongst our employee population. The risk-free rate of the stock options is based on the U.S. Treasury rate in effect at the time of grant for the expected term of the stock options. Estimated forfeitures are based on historical data as well as current trend. Compensation cost incurred during the three and six months ended December 31, 2008 was \$838,000 and \$2.1 million respectively. Compensation cost incurred during the three and six months ended December 31, 2007 was \$546,000 and \$1.1 million respectively. During the three and six months ended December 31, 2008 we recorded approximately \$35,000 and \$747,000, respectively, of compensation expense, which is included in the amounts above, related to the modification of the terms certain of options previously granted to the Chief Executive Officer of the Company in accordance with the succession plan approved by our Board of Directors in September 2008.

As of December 31, 2008, the estimated fair value of unvested employee awards was \$3.7 million, net of estimated forfeitures. The weighted-average remaining vesting period for these awards is approximately two and a half years.

*Investment in Marketable Securities*

We invest in marketable securities of highly rated financial institutions and investment-grade debt instruments and limit the amount of credit exposure with any one entity. These investments are accounted for in accordance with Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, or Statement 115. We have classified our marketable securities as available-for-sale and, accordingly, carry such securities at aggregate fair value. In accounting for investments, we evaluate if a decline in the fair value of a marketable security below our cost basis is other-than-temporary, and if so, we record an impairment charge in our consolidated statement of operations. The factors that we consider in our evaluation include the fair market value of the security, the duration and magnitude of the security's decline, and our intent and ability to hold the security to recovery. The determination of whether a loss is other than temporary is highly judgmental and can have a material impact on our results. During the three and six months ended December 31, 2008, we recorded approximately \$266,000 and \$402,000, respectively, in other-than-temporary impairment charges. No similar charges were recorded in the six months ended December 31, 2007.

*Derivatives*

Derivative instruments include a portfolio of short duration foreign currency forward contracts intended to mitigate the risk of exchange fluctuations for existing or anticipated receivable and payable balances denominated in foreign currency. Derivatives are estimated at fair value and classified as other current assets or liabilities in the accompanying consolidated balance sheets. The fair value of these instruments represents the present value of estimated future cash flows under the contracts, which are a function of underlying interest rates, currency rates, related volatility, counterparty creditworthiness and duration of the contracts. Changes in these factors or a combination thereof may affect the

fair value of these instruments.

We do not designate foreign currency forward contracts as hedges for accounting purposes, and changes in the fair value of these instruments are recognized in earnings during the period of change. Because we enter into forward contracts only as an economic hedge, any gain or loss on the underlying foreign-denominated existing or anticipated receivable or payable balance would be offset by the loss or gain on the forward contract. For the three and six months ended December 31, 2008, net losses recognized on forward contracts were \$79,000 and \$182,000, respectively, and are included in the accompanying consolidated statement of operations as other (loss) income, net. As of December 31, 2008, we had outstanding forward contracts with amounts equivalent to approximately \$3.4 million (2.6 million in Euros), all maturing on or before February 27, 2009. As of June 30, 2008, we had outstanding forward contracts with amounts equivalent to approximately \$1.4 million (924,000 in Euros). For the three and six months ended December 31, 2007, net gains recognized on forward contracts were \$49,000 and \$242,000, respectively. As of December 31, 2007, we had outstanding forward contracts with amounts equivalent to approximately \$7.4 million (5.1 million in Euros). We do not anticipate using derivative instruments for any purpose other than hedging our exchange rate exposure.

Table of Contents**RESULTS OF OPERATIONS***Comparison of Three Months ended December 31, 2008 and 2007**Revenues*

Our total revenues for the three months ended December 31, 2008 and 2007 were \$9.3 million and \$9.8 million, respectively. The \$416,000 decrease in revenues in the three months ended December 31, 2008 from the same period in the prior year is attributable to a decrease in research and development support revenue and clinical materials reimbursement revenue, partially offset by an increase in license and milestone fees, all of which are discussed below.

Research and development support was \$2.3 million for the three months ended December 31, 2008 compared with \$3.7 million for the three months ended December 31, 2007. These amounts primarily represent research funding earned based on actual resources utilized under our discovery, development and commercialization agreement with sanofi-aventis, as well as amounts earned for resources utilized under our development and license agreements with Bayer Healthcare, Biogen Idec, Biotest, and Genentech. Under the terms of the sanofi-aventis agreement, we were entitled to receive committed research funding totaling not less than \$79.3 million over the five years of the research collaboration, which included the initial three-year term of the research program ending August 31, 2006 plus the two 12-month extensions beginning September 1, 2006. The two companies subsequently agreed to extend the date of payment through October 31, 2008 to enable completion of previously agreed upon research. Through the end of the research program, we have earned \$81.5 million of committed funding. Subsequent to October 31, 2008, we have performed, and will continue to perform, research on behalf of sanofi-aventis as mutually agreed upon. Also included in research and development support revenue are fees related to samples of research-grade material shipped to collaborators. To date, our development fees represent the direct and overhead costs incurred in producing research-grade materials and developing antibody-specific conjugation processes on behalf of our collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. The amount of development fees we earn is directly related to the number of our collaborators and potential collaborators, the stage of development of our collaborators' product candidates and the resources our collaborators allocate to the development effort. As such, the amount of development fees may vary widely from quarter to quarter and year to year. Total revenue recognized from research and development support from each of our collaborative partners in the three-month periods ended December 31, 2008 and 2007 is included in the following table (in thousands):

Research and Development Support Collaborative Partner:	Three months ended December 31,	
	2008	2007
Bayer	\$ 90	\$ 61
Biogen Idec	169	453
Biotest	429	50
Centocor		189
Genentech	1,595	2,916
sanofi-aventis		3
Other		
Total	\$ 2,283	\$ 3,672

Revenues from license and milestone fees for the three months ended December 31, 2008 increased \$2.1 million to \$4.8 million from \$2.7 million in the same period ended December 31, 2007. Included in license and milestone fees for the three months ended December 31, 2008

## Edgar Filing: IMMUNOGEN INC - Form 10-Q

was a \$4 million milestone related to the initiation of Phase II clinical testing of AVE1642 by sanofi-aventis. Included in license and milestone fees for the three months ended December 31, 2007 was a \$1 million milestone related to the initiation of Phase I clinical testing of SAR3419 and \$500,000 related to an additional preclinical development milestone achieved under the collaboration agreement with sanofi-aventis. Total revenue from license and milestone fees recognized from each of our collaborative partners in the three-month periods ended December 31, 2008 and 2007 is included in the following table (in thousands):

License and Milestone Fees	Three months ended December 31,	
	2008	2007
<b>Collaborative Partner:</b>		
Amgen	\$ 128	\$ 108
Bayer	103	
Biogen Idec	57	39
Biotest	42	42
Centocor	34	
Genentech	43	291
sanofi-aventis	4,359	2,200
<b>Total</b>	<b>\$ 4,766</b>	<b>\$ 2,680</b>

Deferred revenue of \$14.5 million as of December 31, 2008 primarily represents payments received from our collaborators pursuant to our license agreements, which we have yet to earn pursuant to our revenue recognition policy.

Table of Contents

Clinical materials reimbursement decreased by approximately \$1.1 million in the three months ended December 31, 2008, to nearly \$2.3 million from \$3.4 million in the three months ended December 31, 2007. The decrease in clinical materials reimbursement in the current period is primarily related to fewer batches released during the current period and certain collaborators supplying material previously provided by us. We are reimbursed for certain of our direct and overhead costs to produce clinical materials plus, for certain programs, a profit margin. The amount of clinical materials reimbursement we earn, and the related cost of clinical materials charged to research and development expense, is directly related to the number of clinical trials our collaborators are preparing or have underway, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period, if any, during which patients in the trial receive clinical benefit from the clinical materials, and the supply of clinical-grade material to our collaborators for process development and analytical purposes. As such, the amount of clinical materials reimbursement revenue and the related cost of clinical materials charged to research and development expense may vary significantly from quarter to quarter and year to year.

*Research and Development Expenses*

Our net research and development expenses relate to (i) research to evaluate new targets and to develop and evaluate new antibodies, linkers and cytotoxic agents, (ii) preclinical testing of our own and, in certain instances, our collaborators' product candidates, and the cost of our own clinical trials, (iii) development related to clinical and commercial manufacturing processes and (iv) manufacturing operations. Our research and development efforts have been primarily focused in the following areas:

- activities pursuant to our discovery, development and commercialization agreement with sanofi-aventis;
- activities pursuant to our development and license agreements with various other collaborators;
- activities related to the preclinical and clinical development of IMGN901, IMGN242 and IMGN388;
- process development related to production of the huN901 antibody and IMGN901 conjugate for clinical materials;
- process development related to production of the huC242 antibody and IMGN242 conjugate for clinical materials;
- process improvements related to the production of DM1, DM4 and strain development of their precursor, ansamitocin P3;
- funded development activities with contract manufacturers for the huN901 antibody, the huC242 antibody, and DM1, DM4 and their precursor, ansamitocin P3;
- production costs for the supply of the huN901 antibody and the huC242 antibody;
- production costs for the supply of DMx for our and our partners' preclinical and clinical activities;
- operation and maintenance of our conjugate manufacturing facility, including production of our own and our collaborators' clinical materials;
- process improvements to our TAP technology;

- evaluation of potential antigen targets;
- evaluation of internally developed and/or in-licensed product candidates and technologies; and
- development and evaluation of additional cytotoxic agents and linkers.

Research and development expense for the three months ended December 31, 2008 decreased \$270,000 to \$12.9 million from \$13.2 million for the three months ended December 31, 2007. The decrease was primarily due to decreased antibody development and supply costs and lower cost of clinical materials reimbursed, partially offset by increased salaries and related expenses, greater clinical trial costs and lower overhead utilization. The average number of our research and development personnel increased to 183 at December 31, 2008 compared to 173 at December 31, 2007. Research and development salaries and related expenses increased by \$330,000 in the three months ended December 31, 2008 compared to the three months ended December 31, 2007.

We are unable to accurately estimate which potential product candidates, if any, will eventually move into our internal preclinical research program. We are unable to reliably estimate the costs to develop these products as a result of the uncertainties related to discovery research efforts as well as preclinical and clinical testing. Our decision to move a product candidate into the clinical development phase is predicated upon the results of preclinical tests. We cannot accurately predict which, if any, of the discovery stage product candidates will advance from preclinical testing and move into our internal clinical development program. The clinical trial and regulatory approval processes for our product candidates that have advanced or that we intend to advance to clinical testing are lengthy, expensive and uncertain in both timing and outcome. As a result, the pace and timing of the clinical development of our product candidates is highly uncertain and may not ever result in approved products. Completion dates and development costs will vary significantly for each product candidate and are difficult to predict. A variety of factors, many of which are outside our control, could cause or contribute to the prevention or delay of the successful completion of our clinical trials, or delay or prevent our obtaining necessary regulatory approvals. The costs to take a product through clinical trials are dependent upon, among other factors,

Table of Contents

the clinical indications, the timing, size and design of each clinical trial, the number of patients enrolled in each trial, and the speed at which patients are enrolled and treated. Product candidates may be found to be ineffective or to cause unacceptable side effects during clinical trials, may take longer to progress through clinical trials than anticipated, may fail to receive necessary regulatory approvals or may prove impracticable to manufacture in commercial quantities at reasonable cost or with acceptable quality.

The lengthy process of securing FDA approvals for new drugs requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals would materially adversely affect our product development efforts and our business overall. Accordingly, we cannot currently estimate, with any degree of certainty, the amount of time or money that we will be required to expend in the future on our product candidates prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of our clinical trials, we are currently unable to estimate when, if ever, our product candidates that have advanced into clinical testing will generate revenues and cash flows.

We do not track our research and development costs by project. Since we use our research and development resources across multiple research and development projects, we manage our research and development expenses within each of the categories listed in the following table and described in more detail below (in thousands):

Research and Development Expense	Three Months Ended December 31,	
	2008	2007
Research	\$ 3,470	\$ 3,754
Preclinical and Clinical Testing	2,671	1,760
Process and Product Development	1,467	1,482
Manufacturing Operations	5,280	6,162
Total Research and Development Expense	\$ 12,888	\$ 13,158

**Research:** Research includes expenses associated with activities to identify and evaluate new targets and to develop and evaluate new antibodies, linkers and cytotoxic agents for our products and in support of our collaborators. Such expenses primarily include personnel, fees to in-license certain technology, facilities and lab supplies. Research expenses for the three months ended December 31, 2008 decreased \$284,000 to \$3.5 million from \$3.8 million for the three months ended December 31, 2007. The decrease in research and development expenses was primarily the result of a decrease in salaries and related expenses due to a reorganization of departments in March 2008, resulting in lower personnel costs included in research expense for the current period.

**Preclinical and Clinical Testing:** Preclinical and clinical testing includes expenses related to preclinical testing of our own and, in certain instances, our collaborators' product candidates, and the cost of our own clinical trials. Such expenses include personnel, patient enrollment at our clinical testing sites, consultant fees, contract services, and facility expenses. Preclinical and clinical testing expenses for the three months ended December 31, 2008 increased \$911,000 to \$2.7 million compared to \$1.8 million for the three months ended December 31, 2007. This increase is primarily due to an increase in salaries and related expenses due to a reorganization of departments in March 2008 and July 2008, as well as an increase in clinical trial costs.



**Process and Product Development:** Process and product development expenses include costs for development of clinical and commercial manufacturing processes for our own and collaborator compounds. Such expenses include the costs of personnel, contract services and facility expenses. For the three months ended December 31, 2008, total development expenses decreased \$15,000 to \$1.5 million, compared to \$1.5 million for the three months ended December 31, 2007.

**Manufacturing Operations:** Manufacturing operations expense includes costs to manufacture preclinical and clinical materials for our own and our collaborators product candidates, and quality control and quality assurance activities and costs to support the operation and maintenance of our conjugate manufacturing facility. Such expenses include personnel, raw materials for our and our collaborators preclinical studies and clinical trials, development costs with contract manufacturing organizations, manufacturing supplies, and facilities expense. For the three months ended December 31, 2008, manufacturing operations expense decreased \$882,000 to \$5.3 million compared to \$6.2 million in the same period last year. The decrease in the three months ended December 31, 2008 as compared to the three months ended December 31, 2007 was primarily the result of (i) a decrease in antibody development and supply costs due to timing of supply requirements; (ii) a decrease in contract services due primarily to lower DMx development costs for the potential production of later-stage materials; and (iii) a decrease in cost of clinical materials reimbursed due to fewer batches released during the current period, as well as certain collaborators supplying material previously provided by us. Partially offsetting these decreases, salaries and related expenses increased, depreciation and amortization increased due to the build-out of the Norwood facility and equipment purchases, and overhead utilization from the manufacture of clinical materials on behalf of our collaborators decreased. Antibody expense in anticipation of potential future clinical trials, as well as our ongoing trials, was \$327,000 and \$1.6 million in the three months ended December 31, 2008 and 2007, respectively. The process of antibody production is lengthy as is the lead time to establish a satisfactory production process at a vendor. Accordingly, costs incurred related to antibody production have fluctuated from period to period and we expect these cost fluctuations to continue in the future.

Table of Contents*General and Administrative Expenses*

General and administrative expenses for the three months ended December 31, 2008 were flat compared to the three months ended December 31, 2007. Salaries and related expenses increased \$841,000 during the three months ended December 31, 2008 compared to the three months ended December 31, 2007. During the three months ended December 31, 2008, we recorded \$441,000 of compensation expense related to the transition of the Chief Executive Officer of the Company in accordance with the succession plan approved by ImmunoGen's Board of Directors in September 2008. The remaining increase in salaries and related expense is primarily due to higher salary levels and greater stock compensation costs. Offsetting this increase, rent expense for the current three-month period decreased \$841,000. Rent expense for the prior three-month period included rent for both the Waltham and Cambridge facilities as rent expense (not payments) for Waltham began upon initiation of the lease term in October 2007.

*Other (Expense) Income, net*

Other (expense) income, net for the three months ended December 31, 2008 and 2007 is included in the following table (in thousands):

<b>Other (Expense) Income, net</b>	<b>Three Months Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
Interest Income	\$ 142	\$ 676
Other Than Temporary Impairment	(266)	
Other (Loss) Income	(5)	51
Total Other (Expense) Income, net	\$ (129)	\$ 727

*Interest Income*

Interest income for the three months ended December 31, 2008 decreased \$534,000 to \$142,000 from \$676,000 for the three months ended December 31, 2007. The decrease in interest income is primarily the result of lower yields on investments tied to market rates.

*Other than Temporary Impairment*

During the three months ended December 31, 2008, we recognized \$266,000 in charges for the impairment of available-for-sale securities that were determined to be other-than-temporary following a decline in value. No similar charges were recognized during the three months ended December 31, 2007.

*Other (Loss) Income*

## Edgar Filing: IMMUNOGEN INC - Form 10-Q

During the three months ended December 31, 2008 we recorded net losses on forward contracts of \$79,000 compared to net gains on forward contracts of \$49,000 for the three months ended December 31, 2007. We incurred \$67,000 and \$1,000 in foreign currency translation gains related to obligations with non-U.S. dollar-based suppliers during the three months ended December 31, 2008 and 2007, respectively.

### *Comparison of Six Months ended December 31, 2008 and 2007*

#### *Revenues*

Our total revenues for the six months ended December 31, 2008 and 2007 were \$15.5 million and \$21.2 million, respectively. The \$5.7 million decrease in revenues in the three months ended December 31, 2008 from the same period in the prior year is attributable to a decrease in research and development support revenue and clinical materials reimbursement revenue, partially offset by a slight increase in license and milestone fees, all of which are discussed below.

Research and development support was \$5.5 million for the six months ended December 31, 2008 compared with \$8.1 million for the six months ended December 31, 2007. These amounts primarily represent committed research funding earned based on actual resources utilized under our discovery, development and commercialization agreement with sanofi-aventis, as well as amounts earned for resources utilized under our development and license agreements with Bayer Healthcare, Biogen Idec, Biotest, Centocor, and Genentech. Under the terms of the sanofi-aventis agreement, we were entitled to receive committed research funding totaling not less than \$79.3 million over the five years of the research collaboration, which included the initial three-year term of the research program ending August 31, 2006 plus the two 12-month extensions beginning September 1, 2006. The two companies subsequently agreed to extend the date of payment through October 31, 2008 to enable completion of agreed upon research. Through the end of the research program, we have earned \$81.5 million of committed funding. Subsequent to October 31, 2008, we have performed, and will continue to perform, research on behalf of sanofi-aventis as mutually agreed upon. Also included in research and development support revenue

Table of Contents

are fees related to samples of research-grade material shipped to collaborators. To date, our development fees represent the direct and overhead costs incurred in producing research-grade materials and developing antibody-specific conjugation processes on behalf of our collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. The amount of development fees we earn is directly related to the number of our collaborators and potential collaborators, the stage of development of our collaborators' product candidates and the resources our collaborators allocate to the development effort. As such, the amount of development fees may vary widely from quarter to quarter and year to year. Total revenue recognized from research and development support from each of our collaborative partners in the six-month periods ended December 31, 2008 and 2007 is included in the following table (in thousands):

Research and Development Support	Six months ended December 31,	
	2008	2007
Collaborative Partner:		
Bayer	\$ 122	
Biogen Idec	407	105
Biotest	954	879
Centocor		428
Genentech	9	365
sanofi-aventis	3,945	6,327
Other	53	41
Total	\$ 5,490	\$ 8,145

Revenues from license and milestone fees for the six months ended December 31, 2008 increased \$121,000 to \$7.0 million from \$6.9 million in the same period ended December 31, 2007. Included in license and milestone fees for the six months ended December 31, 2008 was a \$4 million milestone related to the initiation of Phase II clinical testing of AVE1642 by sanofi-aventis and a \$500,000 milestone related to the initiation of Phase I clinical testing of BT-062 by Biotest. Also in this period, Millennium Pharmaceuticals and Boehringer Ingelheim agreed to terminate their licenses with us that were no longer being used to develop products and as a result, we recognized as license and milestone fees \$361,000 and \$486,000, respectively, of upfront fees previously deferred. Included in license and milestone fees for the six months ended December 31, 2007 was \$3 million of the \$5 million milestone payment that we received with the initiation of Phase II clinical testing of trastuzumab-DM1, or T-DM1, by Genentech, a \$1 million milestone related to the initiation of Phase I clinical testing of SAR3419 and \$500,000 related to an additional preclinical development milestone achieved under the collaboration agreement with sanofi-aventis. Total revenue from license and milestone fees recognized from each of our collaborative partners in the six-month periods ended December 31, 2008 and 2007 is included in the following table (in thousands):

License and Milestone Fees	Six months ended December 31,	
	2008	2007
Collaborative Partner:		
Amgen	\$ 253	\$ 217
Bayer	103	
Biogen Idec	114	76
Biotest	584	84
Boehringer Ingelheim	486	
Centocor	69	
Genentech	74	3,582
Millennium Pharmaceuticals	361	
sanofi-aventis	4,945	2,909
Total	\$ 6,989	\$ 6,868

## Edgar Filing: IMMUNOGEN INC - Form 10-Q

Clinical materials reimbursement decreased by approximately \$3.2 million in the six months ended December 31, 2008, to \$3.0 million from \$6.2 million in the six months ended December 31, 2007. The decrease in clinical materials reimbursement in the current period is primarily related to fewer batches released during the current period, lower revenue recognized on shipments of DMx to collaborators during the current period, and to a lesser extent, certain collaborators supplying material previously provided by us. We are reimbursed for certain of our direct and overhead costs to produce clinical materials plus, for certain programs, a profit margin. The amount of clinical materials reimbursement we earn, and the related cost of clinical materials charged to research and development expense, is directly related to the number of clinical trials our collaborators are preparing or have underway, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period, if any, during which patients in the trial receive clinical benefit from the clinical materials, and the supply of clinical-grade material to our collaborators for process development and analytical purposes. As such, the amount of clinical materials reimbursement revenue and the related cost of clinical materials charged to research and development expense may vary significantly from quarter to quarter and year to year.

Table of Contents*Research and Development Expenses*

Research and development expense for the six months ended December 31, 2008 increased \$756,000 to \$24.7 million from \$24.0 million for the six months ended December 31, 2007. The increase in research and development expenses was primarily due to (i) increased employee compensation levels; (ii) greater clinical trial costs; (iii) greater contract service expense; (iv) higher facility expenses; and (v) lower overhead utilization from the manufacture of clinical materials on behalf of our collaborators. Partially offsetting these increases, cost of clinical materials reimbursed and antibody development and supply costs decreased during the current period. The average number of our research and development personnel increased to 175 at December 31, 2008 compared to 173 at December 31, 2007. Research and development salaries and related expenses increased by \$627,000 in the six months ended December 31, 2008 compared to the six months ended December 31, 2007. Facilities expense, including depreciation, increased \$377,000 during the six months ended December 31, 2008 as compared to the same period last year. The increase in facilities expense in the current period was principally due to an increase in depreciation and amortization. The increase in depreciation and amortization is due to the leasehold improvements made to the Norwood and Waltham facilities in fiscal 2008, as well as new capital purchases.

Our categories of research and development expenses are listed in the following table and described in more detail below (in thousands):

Research and Development Expense	Six Months Ended December 31,	
	2008	2007
Research	\$ 7,073	\$ 7,558
Preclinical and Clinical Testing	4,913	3,445
Process and Product Development	3,055	2,969
Manufacturing Operations	9,707	10,020
Total Research and Development Expense	\$ 24,748	\$ 23,992

**Research:** Research includes expenses associated with activities to identify and evaluate new targets and to develop and evaluate new antibodies, linkers and cytotoxic agents for our products and in support of our collaborators. Such expenses primarily include personnel, fees to in-license certain technology, facilities and lab supplies. Research expenses for the six months ended December 31, 2008 decreased \$485,000 to \$7.1 million from \$7.6 million for the six months ended December 31, 2007. The decrease in research and development expenses was primarily the result of a decrease in salaries and related expenses due to a reorganization of departments in March 2008 resulting in lower personnel costs included in research expense for the current period.

**Preclinical and Clinical Testing:** Preclinical and clinical testing includes expenses related to preclinical testing of our own and, in certain instances, our collaborators' product candidates, and the cost of our own clinical trials. Such expenses include personnel, patient enrollment at our clinical testing sites, consultant fees, contract services, and facility expenses. Preclinical and clinical testing expenses for the six months ended December 31, 2008 increased \$1.5 million to \$4.9 million compared to \$3.4 million for the six months ended December 31, 2007. This increase is primarily due to an increase in salaries and related expenses due to a reorganization of departments in March 2008 and July 2008, as well as an increase in clinical trial costs.

**Process and Product Development:** Process and product development expenses include costs for development of clinical and commercial manufacturing processes for our own and collaborator compounds. Such expenses include the costs of personnel, contract services and facility expenses. For the six months ended December 31, 2008, total development expenses increased \$86,000 to \$3.1 million, compared to \$3.0 million for the six months ended December 31, 2007.

**Manufacturing Operations:** Manufacturing operations expense includes costs to manufacture preclinical and clinical materials for our own and our collaborator s product candidates, and quality control and quality assurance activities and costs to support the operation and maintenance of our conjugate manufacturing facility. Such expenses include personnel, raw materials for our and our collaborators preclinical studies and clinical trials, development costs with contract manufacturing organizations, manufacturing supplies, and facilities expense. For the six months ended December 31, 2008, manufacturing operations expense decreased \$313,000 to \$9.7 million compared to \$10 million in the same period last year. The decrease in the six months ended December 31, 2008 was primarily the result of a decrease in antibody development and supply costs due to timing of supply requirements and a decrease in cost of clinical materials reimbursed due to fewer batches released and lower costs incurred on shipments of DMx to collaborators during the current period, as well as certain collaborators supplying material previously provided by us. Partially offsetting these decreases, salaries and related expenses increased, depreciation and amortization increased, and overhead utilization from the manufacture of clinical materials on behalf of our collaborators decreased. Antibody expense in anticipation of potential future clinical trials, as well as our ongoing trials, was \$454,000 and \$2.2 million in the six months ended December 31, 2008 and 2007, respectively. The process of antibody production is lengthy as is the lead time to establish a satisfactory production process at a vendor. Accordingly, costs incurred related to antibody production have fluctuated from period to period and we expect these cost fluctuations to continue in the future.

Table of Contents*General and Administrative Expenses*

General and administrative expenses for the six months ended December 31, 2008 increased \$1.2 million to \$7.2 million compared to \$6.0 million for the six months ended December 31, 2007. The increase is primarily due to a \$1.9 million increase in salaries and related expenses. During the six months ended December 31, 2008, we recorded \$1.2 million of compensation expense related to the transition of the Chief Executive Officer of the Company in accordance with the succession plan approved by ImmunoGen's Board of Directors in September 2008. The remaining increase in salaries and related expense is primarily due to increased employee compensation levels and greater stock compensation costs. Partially offsetting this increase, rent expense for the current period decreased \$841,000 as rent expense (not payments) for Waltham began upon initiation of the lease term in October 2007.

*Other (Expense) Income, net*

Other (expense) income, net for the six months ended December 31, 2008 and 2007 is included in the following table (in thousands):

<b>Other (Expense) Income, net</b>	<b>Six Months Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
Interest Income	\$ 445	\$ 1,343
Net Realized Losses on Investments	(33)	
Other Than Temporary Impairment	(402)	
Other (Loss) Income	(123)	197
<b>Total Other (Expense) Income, net</b>	<b>\$ (113)</b>	<b>\$ 1,540</b>

*Interest Income*

Interest income for the six months ended December 31, 2008 decreased \$898,000 to \$445,000 from \$1.3 million for the six months ended December 31, 2007. The decrease in interest income is primarily the result of lower yields on investments tied to market rates.

*Net Realized Losses on Investments*

Net realized losses on investments were \$33,000 for the six months ended December 31, 2008. There were no losses recognized in the six months ended December 31, 2007. The difference is attributable to market conditions and to the timing of investment sales.

*Other than Temporary Impairment*



## Edgar Filing: IMMUNOGEN INC - Form 10-Q

During the six months ended December 31, 2008, we recognized \$402,000 in charges for the impairment of available-for-sale securities that were determined to be other-than-temporary following a decline in value. No similar charges were recognized during the six months ended December 31, 2007.

### ***Other (Loss) Income***

During the six months ended December 31, 2008 we recorded net losses on forward contracts of \$182,000 compared to net gains on forward contracts of \$242,000 for the six months ended December 31, 2007. We incurred \$51,000 in foreign currency translation gains related to obligations with non-U.S. dollar-based suppliers during the six months ended December 31, 2008 compared to \$46,000 in foreign currency translation losses during the same period in the prior year.

### **Liquidity and Capital Resources**

Edgar Filing: IMMUNOGEN INC - Form 10-Q

	2008	December 31, (In thousands)	2007
Cash, cash equivalents and short-term investments	\$	45,911	\$ 48,658
Working capital		39,758	46,030
Shareholders' equity		41,174	53,137
Cash used for operating activities (six months ended)		(377)	(6,855)
Cash provided by investing activities (six months ended)		5,916	7,670
Cash provided by financing activities (six months ended)		268	975

Table of Contents

*Cash Flows*



## Edgar Filing: IMMUNOGEN INC - Form 10-Q

We require cash to fund our operating expenses, including the advancement of our own clinical programs, and to make capital expenditures. Historically, we have funded our cash requirements primarily through equity financings in public markets and payments from our collaborators, including equity investments, license fees and research funding. As of December 31, 2008, we had approximately \$45.9 million in cash and marketable securities. Net cash used in operations was \$377,000 and \$6.9 million for the six months ended December 31, 2008 and 2007, respectively. The principal use of cash in operating activities for all periods presented was to fund our net loss.

Net cash provided by investing activities was \$5.9 million and \$7.7 million for the six months ended December 31, 2008 and 2007, respectively, and substantially represents cash inflows from the sales and maturities of marketable securities partially offset by capital expenditures. Capital expenditures, primarily for the purchase of new equipment, were \$1 million and \$5.3 million for the six-month periods ended December 31, 2008 and 2007, respectively. Capital expenditures during the prior year six-month period also included expenditures for expansion and improvements of our manufacturing plant in Norwood, MA.

During December 2007, we were notified by a fund manager that a fund in which we hold an investment was unable to meet shareholder redemptions on a timely basis. We held approximately \$4.7 million in this fund at December 31, 2008. Although amounts invested are not currently impaired in value, the balance is not readily convertible to cash. We have the option of redeeming our entire investment from the fund in-kind which would consist of individual securities, or remaining in the fund and receiving cash redemptions as cash becomes available in the fund either through maturities or sales of the underlying securities. We opted to stay in the fund and have received \$13.8 million in redemptions since December 2007. In December 2007, we reclassified the balance in this fund from cash and cash equivalents to marketable securities. We expect to receive at least \$3.3 million in redemptions during the remainder of fiscal 2009 and the balance in subsequent periods.

Net cash provided by financing activities was \$268,000 and \$975,000 for the six months ended December 31, 2008 and 2007, respectively, which represents proceeds from the exercise of 109,000 and 554,000 stock options, respectively.

We anticipate that our current capital resources and future collaborator payments will enable us to meet our operational expenses and capital expenditures for the balance of fiscal 2009 and at least a significant portion of the following fiscal year. However, we cannot provide assurance that such collaborative agreement funding will, in fact, be received. Should we not meet some or all of the terms and conditions of our various collaboration agreements, we may be required to pursue additional strategic partners, secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects.

### *Contractual Obligations*

Effective July 27, 2007, we entered into a lease agreement with Intercontinental Fund III for the rental of approximately 89,000 square feet of laboratory and office space at 830 Winter Street, Waltham, MA. We occupied the space on March 24, 2008 and use this space for our corporate headquarters, research and other operations previously located in Cambridge, MA. The initial term of the lease is for twelve years with an option for us to extend the lease for two additional terms of five years. We are required to pay certain operating expenses for the leased premises subject to escalation charges for such expense increases over a base amount.

As part of the lease agreement, we received a construction allowance of up to approximately \$13.3 million to build out laboratory and office space to our specifications. The construction allowance is accounted for as a lease incentive pursuant to FASB Statement No. 13, *Accounting for Leases*, and FASB Technical Bulletin 88-1, *Issues Relating to Accounting for Leases*. Through December 31, 2008, we have recorded \$12 million of leasehold improvements under the construction allowance. Under the terms of the agreement, the remaining \$1.3 million of the construction allowance is to be applied evenly as a credit to rent for the first year.

## Edgar Filing: IMMUNOGEN INC - Form 10-Q

At December 31, 2008, the Company also leases facilities in Norwood and Cambridge, MA under agreements through 2011. The Company is required to pay certain operating expenses for the leased premises subject to escalation charges for certain expense increases over a base amount. The Company entered into a sub-sublease in May 2008 for the entire space in Cambridge, MA through 2011, the remainder of the sublease.

The minimum rental commitments, including real estate taxes and other expenses, for the next five fiscal years under the non-cancelable operating lease agreements discussed above are as follows (in thousands):

2009 (six months remaining)	\$	2,660
2010		6,108
2011		5,671
2012		4,646
2013		4,646
Total minimum lease payments	\$	23,731
Total minimum rental income from sub-sublease		(1,446)
Total minimum lease payments, net	\$	22,285

Table of Contents

We intend to sublease approximately 14,000 rentable square feet of laboratory and office space at 830 Winter Street, Waltham, MA. We have not included any estimated sublease income for the space in Waltham in the table above.

*Forward-Looking Statements*

This quarterly report includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to analyses and other information which are based on forecasts of future results and estimates of amounts that are not yet determinable. There are a number of factors that could cause actual events or results to be significantly different from those described in the forward-looking statements. Forward-looking statements might include, but are not limited to, one or more of the following subjects:

- future products revenues, expenses, liquidity and cash needs;
- anticipated redemptions from an investment fund;
- anticipated agreements with collaboration partners;
- anticipated clinical trial timelines or results;
- anticipated research and product development results;
- projected regulatory timelines;
- descriptions of plans or objectives of management for future operations, products or services;
- forecasts of future economic performance; and
- descriptions or assumptions underlying or relating to any of the above items.

Forward-looking statements can be identified by the fact that they do not relate to historical or current facts. They use words such as anticipate, estimate, expect, project, intend, opportunity, plan, potential, believe or words of similar meaning. They may also use words such as should, could or may. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this report. You should review carefully the risks and uncertainties identified in this Quarterly Report on Form 10-Q, including the cautionary information set forth under Part II, Item 1A., Risk Factors, and our Annual Report on Form 10-K for the year ended June 30, 2008. We may not revise these forward-looking statements to reflect events or circumstances after the date of this report or to reflect the occurrence of unanticipated events.

**ITEM 3. *Quantitative and Qualitative Disclosure about Market Risk***

We maintain an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not own derivative financial instruments in our investment portfolio. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments that would require disclosure under this item.

Our foreign currency hedging program uses forward contracts to manage the foreign currency exposures that exist as part of our ongoing business operations. The contracts are denominated in Euros and have maturities of less than one year. Our foreign currency risk management strategy is principally designed to mitigate the future potential financial impact of changes in the value of transactions, anticipated transactions and balances denominated in foreign currency, resulting from changes in foreign currency exchange rates.

Our market risks associated with changes in foreign currency exchange rates are concentrated primarily in a portfolio of short duration foreign currency forward contracts. Generally, these contracts provide that we receive certain foreign currencies and pay U.S. dollars at specified exchange rates at specified future dates. Although we are exposed to credit and market risk in the event of future nonperformance by a counterparty, management has no reason to believe that such an event will occur.

**ITEM 4.**                    *Controls and Procedures*

(a)        *Disclosure Controls and Procedures*

The Company's management, with the participation of its principal executive officer and principal financial officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, the Company's principal executive officer and principal financial officer have concluded that,



Table of Contents

as of the end of such period, the Company's disclosure controls and procedures were adequate and effective.

(b) *Changes in Internal Controls*

There have not been any changes in the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2008 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Table of Contents

**PART II. OTHER INFORMATION**

**ITEM 1.            *Legal Proceedings***

From time to time we may be a party to various legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

**ITEM 1A.         *Risk Factors***

You should carefully review and consider the information regarding certain factors that could materially affect our business, financial condition or future results set forth under Item 1A. (Risk Factors) in our Annual Report on Form 10-K for the fiscal year ended June 30, 2008. There have been no material changes from the factors disclosed in our 2008 Annual Report on Form 10-K, although we may disclose changes to such factors or disclose additional factors from time to time in our future filings with the Securities and Exchange Commission.

**ITEM 2.            *Unregistered Sales of Equity Securities and Use of Proceeds***

None.

**ITEM 3.            *Defaults Upon Senior Securities***

None.

**ITEM 4.            *Submission of Matters to a Vote of Security Holders***

Our 2008 Annual Meeting of Shareholders was held on November 12, 2008 (the Meeting ). At the Meeting, shareholders fixed the number of Directors constituting the full Board of Directors at eight. The voting results were as follows:

For: 38,246,812

Edgar Filing: IMMUNOGEN INC - Form 10-Q

Against:	821,120
Abstain:	59,420

At the Meeting, the shareholders elected eight Directors as follows:

DIRECTOR	FOR	WITHHELD
Mitchel Sayare, Ph.D.	37,865,350	1,262,002
Daniel M. Junius	37,902,667	1,224,685
David W. Carter	37,706,800	1,420,552
Stephen C. McCluski	37,581,025	1,546,327
Nicole Onetto, MD	37,665,112	1,462,240
Mark Skaletsky	37,544,468	1,582,884
Joseph J. Villafranca, Ph.D.	37,776,413	1,350,939
Richard J. Wallace	37,772,884	1,354,468

At the meeting, the shareholders approved an amendment to the 2006 Employee, Director and Consultant Equity Incentive Plan to increase the number of shares of common stock authorized for issuance thereunder. The voting results were as follows:

For:	13,347,605
Against:	1,626,908
Abstain:	333,105

**ITEM 5. Other Information**

None.

Table of Contents

**ITEM 6.                    *Exhibits***

- 10.1            Severance Agreement dated as of December 1, 2008 between the Registrant and Daniel M. Junius
- 10.2            Severance Agreement dated as of December 1, 2008 between the Registrant and Mitchel Sayare
- 10.3            Severance Agreement dated as of December 1, 2008 between the Registrant and John M. Lambert
- 10.4            Severance Agreement dated as of December 1, 2008 between the Registrant and James J. O Leary
- 10.5            Severance Agreement dated as of January 9, 2009 between the Registrant and Gregory D. Perry
- 10.6            Employment offer letter between the Registrant and Gregory D. Perry
- 10.7\*           Amendment No. 3, dated as of August 31, 2008 to the Collaboration and License Agreement between the Registrant and sanofi-aventis U.S. LLC
- 31.1            Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2            Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.             Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002.

---

(\*) Portions of this Exhibit were omitted, as indicated by [\*\*\*], and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment.

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**ImmunoGen, Inc.**

Date: February 6, 2009

By: /s/ Daniel M. Junius  
Daniel M. Junius  
President, Chief Executive Officer (Principal  
Executive Officer)

Date: February 6, 2009

By: /s/ Gregory D. Perry  
Gregory D. Perry  
Senior Vice President, Chief Financial Officer  
(Principal Financial and Accounting  
Officer)

Table of Contents

**INDEX TO EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>
10.1	Severance Agreement dated as of December 1, 2008 between the Registrant and Daniel M. Junius
10.2	Severance Agreement dated as of December 1, 2008 between the Registrant and Mitchel Sayare
10.3	Severance Agreement dated as of December 1, 2008 between the Registrant and John M. Lambert
10.4	Severance Agreement dated as of December 1, 2008 between the Registrant and James J. O Leary
10.5	Severance Agreement dated as of January 9, 2009 between the Registrant and Gregory D. Perry
10.6	Employment offer letter between the Registrant and Gregory D. Perry
10.7	Amendment No. 3, dated as of August 31, 2008 to the Collaboration and License Agreement between the Registrant and sanofi-aventis U.S. LLC
31.1	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.	Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002.

---

(\*) Portions of this Exhibit were omitted, as indicated by [\*\*\*], and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment.