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.

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. **x** Yes **o** 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 **o** Non-accelerated filer **o**(Do not check if a smaller reporting company) Accelerated filer **x** Smaller reporting company **0**

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

o Yes x 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.

IMMUNOGEN, INC.

FORM 10-Q

FOR THE QUARTER ENDED DECEMBER 31, 2008

TABLE OF CONTENTS

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

Table of Contents

ITEM 1. Financial Statements

IMMUNOGEN, INC.

CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

In thousands, except per share amounts

	D	ecember 31, 2008	June 30, 2008
ASSETS			
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
LIABILITIES AND SHAREHOLDERS EQUITY		,	,
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

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

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
Revenues:							
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
Operating Expenses:							
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) \$	6 (16,500)	\$	(7,244)
Basic and diluted net loss per common share	\$	(0.14)	\$	(0.15) \$	6 (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.

IMMUNOGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

In thousands, except per share amounts

	Six months ender 2008	ber 31, 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

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

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 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

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 peri

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):

	Fair Value Measurements at December 31, 2008 Using Quoted Prices in Active Markets for Significant Other Identical Assets Observable Inputs					Significant nobservable Inputs
	Total		(Level 1)		(Level 2)	(Level 3)
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):

	December 31, 2008			June 30, 2008		
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.

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 Decembe	
	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 December		Six Months Ended December 31,		
	2008 2007			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 fluctuations 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 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:

	Three Months December		Six Months Ended December 31,		
Collaborative Partner:	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

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.

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 –