

IMMUNOGEN INC
Form 10-Q
October 30, 2014
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2014

OR

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 has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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

Accelerated filer

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

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: 85,935,634 shares outstanding as of October 23, 2014.

Table of Contents

IMMUNOGEN, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2014

TABLE OF CONTENTS

Item	Page Number
Part I	
<u>1. Financial Statements (Unaudited):</u>	
<u>1a. Consolidated Balance Sheets as of September 30, 2014 and June 30, 2014</u>	2
<u>1b. Consolidated Statements of Operations and Comprehensive Loss for the three months ended September 30, 2014 and 2013</u>	3
<u>1c. Consolidated Statements of Cash Flows for the three months ended September 30, 2014 and 2013</u>	4
<u>1d. Notes to Consolidated Financial Statements</u>	5
<u>2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>3. Quantitative and Qualitative Disclosures about Market Risk</u>	24
<u>4. Controls and Procedures</u>	24
Part II	
<u>1A. Risk Factors</u>	25
<u>6. Exhibits</u>	26
<u>Signatures</u>	27

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

	September 30, 2014	June 30, 2014
ASSETS		
Cash and cash equivalents	\$ 121,798	\$ 142,261
Accounts receivable	1,838	1,896
Unbilled revenue	784	1,329
Inventory	2,115	2,950
Prepaid and other current assets	1,795	2,320
Total current assets	128,330	150,756
Property and equipment, net of accumulated depreciation	14,668	14,349
Other assets	108	213
Total assets	\$ 143,106	\$ 165,318
LIABILITIES AND SHAREHOLDERS EQUITY		
Accounts payable	\$ 4,957	\$ 4,819
Accrued compensation	3,712	6,865
Other accrued liabilities	6,844	6,668
Current portion of deferred lease incentive	562	528
Current portion of deferred revenue	23,699	2,374
Total current liabilities	39,774	21,254
Deferred lease incentive, net of current portion	5,904	5,679
Deferred revenue, net of current portion	34,661	58,969
Other long-term liabilities	3,796	3,717
Total liabilities	84,135	89,619
Commitments and contingencies (Note E)		
Shareholders' equity:		
Preferred stock, \$0.01 par value; authorized 5,000 shares; no shares issued and outstanding		
Common stock, \$0.01 par value; authorized 150,000 shares; issued and outstanding 85,928 and 85,903 shares as of September 30, 2014 and June 30, 2014, respectively	859	859
Additional paid-in capital	728,525	722,971
Accumulated deficit	(670,413)	(648,131)
Total shareholders' equity	58,971	75,699
Total liabilities and shareholders' equity	\$ 143,106	\$ 165,318

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

Table of Contents

IMMUNOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

In thousands, except per share amounts

	Three Months Ended September 30,	
	2014	2013
Revenues:		
License and milestone fees	\$ 6,234	\$ 13,167
Royalty revenue	4,166	2,053
Research and development support	776	1,990
Clinical materials revenue	2,027	8
Total revenues	13,203	17,218
Operating Expenses:		
Research and development	28,018	22,029
General and administrative	7,095	6,526
Total operating expenses	35,113	28,555
Loss from operations	(21,910)	(11,337)
Other (expense) income, net	(372)	111
Net loss	\$ (22,282)	\$ (11,226)
Basic and diluted net loss per common share	\$ (0.26)	\$ (0.13)
Basic and diluted weighted average common shares outstanding	85,872	85,010
Total comprehensive loss	\$ (22,282)	\$ (11,226)

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

	Three Months ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$ (22,282)	\$ (11,226)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	1,389	1,162
Loss (gain) on sale/disposal of fixed assets		20
Gain on forward contracts		(2)
Stock and deferred share unit compensation	5,410	4,795
Deferred rent	92	(6)
Changes in operating assets and liabilities:		
Accounts receivable	58	(5,789)
Unbilled revenue	545	142
Inventory	835	(968)
Prepaid and other current assets	525	(559)
Other assets	105	14
Accounts payable	138	(1,376)
Accrued compensation	(3,153)	(2,877)
Other accrued liabilities	29	438
Deferred revenue	(2,983)	(7,343)
Proceeds from landlord for tenant improvements	393	
Net cash used for operating activities	(18,899)	(23,575)
Cash flows from investing activities:		
Purchases of property and equipment, net	(1,708)	(572)
Net cash used for investing activities	(1,708)	(572)
Cash flows from financing activities:		
Proceeds from stock options exercised	144	4,025
Net cash provided by financing activities	144	4,025
Net change in cash and cash equivalents	(20,463)	(20,122)
Cash and cash equivalents, beginning balance	142,261	194,960
Cash and cash equivalents, ending balance	\$ 121,798	\$ 174,838

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

Table of Contents

IMMUNOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2014

A. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements at September 30, 2014 and June 30, 2014 and for the three months ended September 30, 2014 and 2013 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 periods. 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, 2014.

Subsequent Events

The Company has evaluated all events or transactions that occurred after September 30, 2014 up through the date the Company issued these financial statements. In October 2014, Novartis took three licenses under its right-to-test agreement with the Company, triggering a \$3 million payment in exercise fees to the Company. The exercise by Novartis of its rights to take these licenses will result in \$25.7 million in license and milestone fee revenue to be recorded by the Company in the second quarter of fiscal 2015, inclusive of the \$3 million of exercise fees for these licenses and the amortization of the remaining portion of the upfront fee allocated to the development and commercialization licenses paid by Novartis with the establishment of the right-to-test agreement in fiscal 2011. Novartis has now taken all licenses permitted under its right-to-test agreement with the Company. The Company did not have any other material recognizable or unrecognizable subsequent events during this period.

Revenue Recognition

The Company enters into licensing and development agreements with collaborative partners for the development of monoclonal antibody-based anticancer therapeutics. The terms of these agreements contain multiple deliverables which may include (i) licenses, or options to obtain licenses, to the Company's antibody-drug conjugate, or ADC, technology, (ii) rights to future technological improvements, (iii) research activities to be performed on behalf of the collaborative partner, (iv) delivery of cytotoxic agents and (v) the manufacture of preclinical or clinical

Edgar Filing: IMMUNOGEN INC - Form 10-Q

materials for the collaborative partner. Payments to the Company under these agreements may include upfront fees, option fees, exercise fees, payments for research activities, payments for the manufacture of preclinical or clinical materials, payments based upon the achievement of certain milestones and royalties on product sales. The Company follows the provisions of the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 605-25, Revenue Recognition Multiple-Element Arrangements, and ASC Topic 605-28, Revenue Recognition Milestone Method, in accounting for these agreements. In order to account for these agreements, the Company must identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on if certain criteria are met, including whether the delivered element has stand-alone value to the collaborator. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units.

At September 30, 2014, the Company had the following two types of agreements with the parties identified below:

- Development and commercialization licenses to use the Company's ADC technology and/or certain other intellectual property to develop compounds to a specified target antigen (referred to as development and commercialization licenses, as distinguished from the Company's right-to-test agreements described elsewhere):

Table of Contents

Amgen (four exclusive single-target licenses(1))

Bayer HealthCare (one exclusive single-target license)

Biotest (one exclusive single-target license)

Lilly (one exclusive single-target license)

Novartis (two exclusive single-target licenses and one license to two related targets: one target on an exclusive basis and the second target on a non-exclusive basis)

Roche, through its Genentech unit (five exclusive single-target licenses)

Sanofi (one exclusive single-target license and one exclusive license to multiple individual targets)

- Research license/option agreement for a defined period of time to secure development and commercialization licenses to use the Company's ADC technology to develop anticancer compounds to specified targets on established terms (referred to herein as right-to-test agreements):

Sanofi

Novartis

Lilly

CytomX

There are no performance, cancellation, termination or refund provisions in any of the arrangements that contain material financial consequences to the Company.

Development and Commercialization Licenses

The deliverables under a development and commercialization license agreement generally include the license to the Company's ADC technology with respect to a specified antigen target, and may also include deliverables related to rights to future technological improvements, research activities to be performed on behalf of the collaborative partner and the manufacture of preclinical or clinical materials for the collaborative partner.

Generally, development and commercialization licenses contain non-refundable terms for payments and, depending on the terms of the agreement, provide that the Company will (i) at the collaborator's request, provide research services at negotiated prices which are generally consistent with what other third parties would charge, (ii) at the collaborator's request, manufacture and provide to it preclinical and clinical materials or deliver cytotoxic agents at negotiated prices which are generally consistent with what other third parties would charge, (iii) earn payments upon the achievement of certain milestones and (iv) earn royalty payments, generally until the later of the last applicable patent expiration or 10 to 12 years after product launch. In the case of Kadcyla®, however, the royalty term, on a country-by-country basis, is 10 years after product launch, which may be extended an additional two years, for a maximum royalty term of 12 years, depending on patent protection as of the end of the initial 10-year royalty term. Royalty rates may vary over the royalty term depending on the Company's intellectual property rights and/or the presence of comparable competing products. The Company may provide technical assistance and share any technology improvements with its collaborators during the term of the collaboration agreements. The Company does not directly control when or whether any collaborator will request research or manufacturing services, achieve milestones or become liable for royalty payments. As a result, the Company cannot predict when or if it will recognize revenues in connection with any of the foregoing.

In determining the units of accounting, management evaluates whether the license has stand-alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of ADC technology research expertise in the general marketplace. If the Company concludes that the license has stand-alone value and therefore will be accounted

(1) Amgen has sublicensed one of its exclusive single-target licenses to Oxford BioTherapeutics Ltd.

Table of Contents

for as a separate unit of accounting, the Company then determines the estimated selling prices of the license and all other units of accounting based on market conditions, similar arrangements entered into by third parties, and entity-specific factors such as the terms of the Company's previous collaborative agreements, recent preclinical and clinical testing results of therapeutic products that use the Company's ADC technology, the Company's pricing practices and pricing objectives, the likelihood that technological improvements will be made, and, if made, will be used by the Company's collaborators and the nature of the research services to be performed on behalf of its collaborators and market rates for similar services.

Upfront payments on development and commercialization licenses are deferred if facts and circumstances dictate that the license does not have stand-alone value. Prior to the adoption of Accounting Standards Update (ASU) No. 2009-13, Revenue Arrangements with Multiple Deliverables on July 1, 2010, the Company determined that its licenses lacked stand-alone value and were combined with other elements of the arrangement and any amounts associated with the license were deferred and amortized over a certain period, which the Company refers to as the Company's period of substantial involvement. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period. Historically the Company's involvement with the development of a collaborator's product candidate has been significant at the early stages of development, and lessens as it progresses into clinical trials. Also, as a drug candidate gets closer to commencing pivotal testing the Company's collaborators have sought an alternative site to manufacture their products, as the Company's facility does not produce pivotal or commercial drug product. Accordingly, the Company generally estimates this period of substantial involvement 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 substantial 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 and makes adjustments as appropriate. In the event a collaborator elects to discontinue development of a specific product candidate under a development and commercialization 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 its remaining period of substantial involvement can be estimated. In the event that a development and commercialization 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.

Subsequent to the adoption of ASU No. 2009-13, the Company determined that its research licenses lack stand-alone value and are considered for aggregation with the other elements of the arrangement and accounted for as one unit of accounting.

Upfront payments on development and commercialization licenses may be recognized upon delivery of the license if facts and circumstances dictate that the license has stand-alone value from the undelivered elements, which generally include rights to future technological improvements, research services, delivery of cytotoxic agents and the manufacture of preclinical and clinical materials.

The Company recognizes revenue related to research services that represent separate units of accounting 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 Company recognizes revenue related to the rights to future technological improvements over the estimated term of the applicable license.

The Company may also provide cytotoxic agents to its collaborators or produce preclinical and clinical materials at negotiated prices which are generally consistent with what other third parties would charge. The Company recognizes revenue on cytotoxic agents and 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. Arrangement consideration allocated to the manufacture of preclinical and clinical materials in a multiple-deliverable arrangement is below the Company's full cost, and the Company's full cost is not expected to ever be below its contract selling prices for its existing collaborations. During the three months ended September 30, 2014, the difference between the Company's full cost to manufacture preclinical and clinical materials on behalf of its collaborators as compared to total amounts received from collaborators for the

Edgar Filing: IMMUNOGEN INC - Form 10-Q

manufacture of preclinical and clinical materials was \$3.1 million. There were no sales of manufactured preclinical or clinical materials during the three months ended September 30, 2013. The majority of the Company's costs to produce these preclinical and clinical materials are fixed and then allocated to each batch based on the number of batches produced during the period. Therefore, the Company's costs to produce these materials are significantly impacted by the number of batches produced during the period. The volume of preclinical and clinical materials the Company produces is directly related to the number of clinical trials the Company and its collaborators are preparing for or currently have underway, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period such trials last. Accordingly, the volume of preclinical and clinical materials produced, and therefore the Company's per-batch costs to manufacture these preclinical and clinical materials, may vary significantly from period to period.

Table of Contents

The Company may also produce 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. The Company records amounts received for research materials produced or services performed as a component of research and development support revenue. The Company also develops conjugation processes for materials for later stage testing and commercialization for certain collaborators. The Company is compensated at negotiated rates and may receive milestone payments for developing these processes which are recorded as a component of research and development support revenue.

The Company's development and commercialization license agreements have milestone payments which for reporting purposes are aggregated into three categories: (i) development milestones, (ii) regulatory milestones, and (iii) sales milestones. Development milestones are typically payable when a product candidate initiates or advances into different clinical trial phases. Regulatory milestones are typically payable upon submission for marketing approval with the U.S. Food and Drug Administration, or FDA, or other countries' regulatory authorities or on receipt of actual marketing approvals for the compound or for additional indications. Sales milestones are typically payable when annual sales reach certain levels.

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

Non-refundable development and regulatory milestones that are expected to be achieved as a result of the Company's efforts during the period of substantial involvement are considered substantive and are recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive because we do not contribute effort to the achievement of such milestones are generally achieved after the period of substantial involvement and are recognized as revenue upon achievement of the milestone, as there are no undelivered elements remaining and no continuing performance obligations, assuming all other revenue recognition criteria are met.

Under the Company's development and commercialization license agreements, the Company receives royalty payments based upon its licensees net sales of covered products. Generally, under these agreements the Company is to receive royalty reports and payments from its licensees approximately one quarter in arrears, that is, generally in the second month of the quarter after the licensee has sold the royalty bearing product or products. The Company recognizes royalty revenues when it can reliably estimate such amounts and collectability is reasonably assured. As such, the Company generally recognizes royalty revenues in the quarter reported to the Company by its licensees, or one quarter following the quarter in which sales by the Company's licensees occurred.

Right-to-Test Agreements

The Company's right-to-test agreements provide collaborators the right to (a) test the Company's ADC technology for a defined period of time through a research, or right-to-test, license, (b) take a defined number of options, for a defined period of time, to specified targets and (c) upon

Edgar Filing: IMMUNOGEN INC - Form 10-Q

exercise of an option, secure or take a license to develop and commercialize products for the specified targets on established terms. Under these agreements, fees may be due to the Company (i) at the inception of the arrangement (referred to as upfront fees or payments), (ii) upon taking an option with respect to a specific target (referred to as option fees or payments earned, if any, when the option is taken), (iii) upon the exercise of a previously taken option to acquire a development and commercialization license(s) (referred to as exercise fees or payments earned, if any, when the development and commercialization license is taken), or (iv) some combination of all of these fees.

The accounting for right-to-test agreements is dependent on the nature of the options granted to the collaborative partner. Options are considered substantive if, at the inception of a right-to-test agreement, the Company is at risk as to whether the collaborative partner will choose to exercise the options to secure development and commercialization licenses. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options.

Table of Contents

For right-to-test agreements where the options to secure development and commercialization licenses to the Company's ADC technology are considered substantive, the Company does not consider the development and commercialization licenses to be a deliverable at the inception of the agreement. For those right-to-test agreements entered into prior to the adoption of ASU No. 2009-13 where the options to secure development and commercialization licenses are considered substantive, the Company has deferred the upfront payments received and recognizes this revenue over the period during which the collaborator could elect to take options for development and commercialization licenses. These periods are specific to each collaboration agreement. If a collaborator takes an option to acquire a development and commercialization license under these agreements, any substantive option fee is deferred and recognized over the life of the option, generally 12 to 18 months. If a collaborator exercises an option and takes a development and commercialization license to a specific target, the Company attributes the exercise fee to the development and commercialization license. Upon exercise of an option to acquire a development and commercialization license, the Company would also attribute any remaining deferred option fee to the development and commercialization license and apply the multiple-element revenue recognition criteria to the development and commercialization license and any other deliverables to determine the appropriate revenue recognition, which will be consistent with the Company's accounting policy for upfront payments on single-target licenses. In the event a right-to-test 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. None of the Company's right-to-test agreements entered into subsequent to the adoption of ASU No. 2009-13 has been determined to contain substantive options.

For right-to-test agreements where the options to secure development and commercialization licenses to the Company's ADC technology are not considered substantive, the Company considers the development and commercialization licenses to be a deliverable at the inception of the agreement and applies the multiple-element revenue recognition criteria to determine the appropriate revenue recognition. None of the Company's right-to-test agreements entered into prior to the adoption of ASU No. 2009-13 has been determined to contain non-substantive options.

The Company does not directly control when or if any collaborator will exercise its options for development and commercialization licenses. As a result, the Company cannot predict when or if it will recognize revenues in connection with any of the foregoing.

Fair Value of Financial Instruments

Fair value is defined under ASC Topic 820, Fair Value Measurements and Disclosures, 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 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.

Edgar Filing: IMMUNOGEN INC - Form 10-Q

- 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 September 30, 2014, the Company held certain assets that are required to be measured at fair value on a recurring basis. The following table represents the fair value hierarchy for the Company's financial assets measured at fair value on a recurring basis as of September 30, 2014 (in thousands):

	Total	Fair Value Measurements at September 30, 2014 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents	\$ 121,798	\$ 121,798	\$	\$

Table of Contents

As of June 30, 2014, the Company held certain assets that are required to be measured at fair value on a recurring basis. The following table represents the fair value hierarchy for the Company's financial assets measured at fair value on a recurring basis as of June 30, 2014 (in thousands):

	Total	Fair Value Measurements at June 30, 2014 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	\$ 142,261	\$ 142,261	\$	\$

The fair value of the Company's cash equivalents is based primarily on quoted prices from active markets.

Unbilled Revenue

The majority of the Company's unbilled revenue at September 30, 2014 and June 30, 2014 represents research funding earned prior to those dates based on actual resources utilized under the Company's agreements with various collaborators.

Inventory

Inventory costs 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 September 30, 2014 and June 30, 2014 is summarized below (in thousands):

	September 30, 2014	June 30, 2014
Raw materials	\$ 269	\$ 437
Work in process	1,846	2,513
Total	\$ 2,115	\$ 2,950

Raw materials inventory consists entirely of DM1 and DM4, proprietary cell-killing agents the Company developed as part of its ADC technology. The Company considers more than a twelve month supply of raw materials that is not supported by firm, fixed orders and/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. In accordance with this policy, the Company recorded \$337,000 and \$135,000 of expense related to excess inventory during the three-month periods ended September 30, 2014 and 2013, respectively.

Work in process inventory consists of conjugate manufactured for sale to the Company's collaborators to be used in preclinical and clinical studies. All conjugate is made to order at the request of the collaborators and subject to the terms and conditions of respective supply agreements. As such, no reserve for work in process inventory is required.

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. During periods of income, participating securities are allocated a proportional share of income determined by dividing total weighted average participating securities by the sum of the total weighted average common shares and participating securities (the two-class method). The Company's restricted stock participates in any dividends declared by the Company and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is allocated to participating securities since they have no contractual obligation to share in the losses of the Company. The impact of applying the two-class method was not material. Diluted (loss) income per share is computed after giving consideration to the dilutive effect of stock options that are outstanding during the period, except where such non-participating securities would be anti-dilutive.

The Company's common stock equivalents, as calculated in accordance with the treasury-stock method, are shown in the following table (in thousands):

Table of Contents

	Three Months Ended September 30,	
	2014	2013
Options outstanding to purchase common stock and unvested restricted stock	10,564	8,733
Common stock equivalents under treasury stock method	1,147	2,215

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.

Stock-Based Compensation

As of September 30, 2014, 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. At the annual meeting of shareholders on November 13, 2012, an amendment to the 2006 Plan was approved and an additional 3,500,000 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 12,000,000 shares of the Company's common stock, as well as 1,676,599 shares of common stock which represent awards granted under the previous stock option plan, the ImmunoGen, Inc. Restated Stock Option Plan, or the Former Plan, that were forfeited, expired or were cancelled without delivery of shares of common stock or which resulted in the forfeiture of shares of common stock back to the Company between November 11, 2006 and June 30, 2014. 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.

The stock-based awards are accounted for under ASC Topic 718, Compensation - Stock Compensation. Pursuant to Topic 718, the estimated grant date fair value of awards is charged to the statement of operations and comprehensive loss over the requisite service period, which is the vesting period. Such amounts have been reduced by an 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 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 option recipients. 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 September 30,	
	2014	2013
Dividend	None	None
Volatility	60.44%	60.44%
Risk-free interest rate	1.88%	1.69%
Expected life (years)	6.3	6.3

Using the Black-Scholes option-pricing model, the weighted average grant date fair values of options granted during the three months ended September 30, 2014 and 2013 were \$6.27 and \$10.93 per share, respectively.

Stock compensation expense related to stock options and restricted stock awards granted under the 2006 Plan was \$5.3 million and \$4.7 million during the three months ended September 30, 2014 and 2013, respectively. As of September 30, 2014, the estimated fair value of unvested employee awards was \$28.8 million, net of estimated forfeitures. The weighted-average remaining vesting period for these awards is approximately two and a half years.

During the three months ended September 30, 2014, holders of options issued under the Company's equity plans exercised their rights to acquire an aggregate of approximately 25,000 shares of common stock at prices ranging from \$3.19 to \$9.88 per share. The total proceeds to the Company from these option exercises were approximately \$144,000.

Table of Contents

Financial Instruments and Concentration of Credit Risk

The Company's cash equivalents consist of money market funds with underlying investments primarily being U.S. Government-issued securities and high quality, short-term commercial paper. All of the Company's cash and cash equivalents are maintained with three financial institutions in the U.S. The Company uses a Euro-denominated bank account to manage the foreign currency exposures that exist as part of our ongoing business operations. 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.

Segment Information

During the three months ended September 30, 2014, the Company continued to operate in one operating segment which is the business of discovery of monoclonal antibody-based anticancer therapeutics.

The percentages of revenues recognized from significant customers of the Company in the three months ended September 30, 2014 and 2013 are included in the following table:

Collaborative Partner:	Three Months Ended September 30,	
	2014	2013
Biotest	11%	1%
Lilly	3%	49%
Roche	32%	41%
Sanofi	45%	1%

There were no other customers of the Company with significant revenues in the three months ended September 30, 2014 and 2013.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update 2014-9, *Revenue from Contracts with Customers (Topic 606)*, to clarify the principles for recognizing revenue. This update provides a comprehensive new revenue recognition model that requires revenue to be recognized in a manner to depict the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, and allows for either full retrospective or modified retrospective application, with early adoption not permitted. Accordingly, the standard is effective for the Company on July 1, 2017. The Company is currently evaluating the adoption method it will apply and the impact that this guidance will have on our financial statements and related disclosures.

B. Collaborative Agreements

Roche

In May 2000, the Company granted Genentech, now a unit of Roche, an exclusive license to use the Company's maytansinoid ADC technology with antibodies, such as trastuzumab, or other proteins that target HER2. Under the terms of this agreement, Roche has exclusive worldwide rights to develop and commercialize maytansinoid ADC compounds targeting HER2. In February 2013, the U.S. FDA granted marketing approval to the HER2-targeting ADC compound, Kadcyla. Roche received marketing approval for Kadcyla in Japan and in the European Union (EU) in September 2013 and November 2013, respectively, and began marketing kadeyla in Japan in April 2014 and in the first EU countries in early 2014. Roche is responsible for the manufacturing, product development and marketing of Kadcyla and any other products resulting from the agreement. The Company received a \$2 million non-refundable upfront payment from Roche upon execution of the agreement. The Company is also entitled to receive up to a total of \$44 million in milestone payments, plus royalties on the commercial sales of Kadcyla or any other resulting products. Total milestones are categorized as follows: development milestones \$13.5 million; and regulatory milestones \$30.5 million. Through September 30, 2014, the Company has received and recognized \$13.5 million and \$20.5 million in development and regulatory milestone payments, respectively, related to Kadcyla, including a \$5 million regulatory milestone for the marketing approval of Kadcyla in Japan which is included in license and milestone fees for the three months ended September 30, 2013. Based on an evaluation of the effort contributed to the achievement of this milestone, the Company determined this milestone was not substantive. In consideration that there were no undelivered elements remaining, no continuing performance obligations and all other revenue recognition criteria had been met, the Company recognized the \$5 million non-refundable payment as revenue upon achievement of the milestone. The next potential milestone the Company will be entitled to receive will be a

Table of Contents

\$5 million regulatory milestone for marketing approval of Kadcylla for a first extended indication as defined in the agreement. Based on an evaluation of the effort contributed towards the achievement of this future milestone, the Company determined this milestone is not substantive.

The Company receives royalty reports and payments related to sales of Kadcylla from Roche one quarter in arrears. In accordance with the Company's revenue recognition policy, \$4.2 million of royalties on net sales of Kadcylla for the three-month period ended June 30, 2014 were recorded and included in royalty revenue for the three months ended September 30, 2014 compared to \$2.1 million of royalties on net sales of Kadcylla for the three-month period ended June 30, 2013 which is included in royalty revenue for the three months ended September 30, 2013.

Sanofi

In July 2003, the Company entered into a broad collaboration agreement with Sanofi (formerly Aventis) to discover, develop and commercialize antibody-based products. The collaboration agreement provides Sanofi with worldwide development and commercialization rights to new antibody-based products directed to targets that are included in the collaboration, including the exclusive right to use the Company's maytansinoid ADC technology in the creation of products developed to these targets. The product candidates (targets) as of September 30, 2014 in the collaboration include SAR3419 (CD19), SAR650984 (CD38), SAR566658 (CA6), SAR408701 (CEACAM5) and one earlier-stage compound that has yet to be disclosed.

The Company is entitled to receive milestone payments potentially totaling \$21.5 million, per target, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$7.5 million; and regulatory milestones \$14 million. Through September 30, 2014, the Company has received and recognized an aggregate of \$20.5 million in milestone payments for compounds covered under this agreement now or in the past, including a \$3 million development milestone related to initiation of a Phase IIb clinical trial (as defined in the agreement) for SAR650984 and a \$1 million development milestone related to initiation of a Phase I clinical trial for SAR408701 which are included in license and milestone fee revenue for the three months ended September 30, 2014. The next potential milestone the Company will be entitled to receive for each of SAR566658 and SAR408701 will be a development milestone for initiation of a Phase IIb clinical trial (as defined in the agreement), which will result in each case in a \$3 million payment being due. The next potential milestone the Company will be entitled to receive with respect to both SAR3419 and SAR650984 will be a development milestone for initiation of a Phase III clinical trial, which will result in each case in a \$3 million payment being due. The next potential milestone the Company will be entitled to receive for the unidentified target will be a development milestone for commencement of a Phase I clinical trial, which will result in a \$1 million payment being due. At the time of execution of this agreement, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's past involvement in the research and manufacturing of these product candidates, these milestones were deemed substantive.

In December 2006, the Company entered into a right-to-test agreement with Sanofi. The agreement provides Sanofi with the right to (a) test the Company's maytansinoid ADC technology with Sanofi's antibodies to targets under a right-to-test, or research, license, (b) take exclusive options, with certain restrictions, to specified targets for specified option periods and (c) upon exercise of those options, take exclusive licenses to use the Company's maytansinoid ADC technology to develop and commercialize products directed to the specified targets on terms agreed upon at the inception of the right-to-test agreement. Sanofi no longer has the right to take additional options under the agreement, although multiple outstanding options remain in effect for the remainder of their respective option periods. For each development and commercialization license taken, the Company is entitled to receive an exercise fee of \$2 million and up to a total of \$30 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$10 million; and regulatory milestones \$20 million. Sanofi is responsible for the manufacturing, product development and marketing of any products resulting from the agreement.

Edgar Filing: IMMUNOGEN INC - Form 10-Q

In December 2013, Sanofi took its first exclusive development and commercialization license under the right-to-test agreement, for which the Company received an exercise fee of \$2 million and was recognizing this amount as revenue ratably over the Company's estimated period of its substantial involvement. The Company had previously estimated this development period would conclude at the end of non-pivotal Phase II testing. During the current quarter, the Company determined it will not be substantially involved in the development and commercialization of the product based on Sanofi's current plans to develop and manufacture the product without the assistance of the Company. As a result of this determination, the Company recognized the balance of the upfront exercise fee during the current quarter. This change in estimate results in an increase to license and milestone fees of \$1.7 million for the three months ended September 30, 2014 compared to amounts that would have been recognized pursuant to the Company's previous estimate. The next payment the Company could receive would either be a \$2 million development milestone payment with the initiation of a Phase I clinical trial under the first development and commercialization license taken, or a \$2 million exercise fee for the execution of a second license. At the time of execution of this agreement, there was significant uncertainty as to whether the

Table of Contents

milestone related to initiation of a Phase I clinical trial under the first development and commercialization license would be achieved. In consideration of this, as well as the Company's expected involvement in the research and manufacturing of these product candidates, this milestone was deemed substantive.

Lilly

In December 2011, the Company entered into a three-year right-to-test agreement with Eli Lilly and Company (Lilly). The agreement provides Lilly with the right to (a) take exclusive options, with certain restrictions, to individual targets selected by Lilly for specified option periods, (b) test the Company's maytansinoid ADC technology with Lilly's antibodies directed to the optioned targets under a right-to-test, or research, license, and (c) upon exercise of those options, take exclusive licenses to use the Company's maytansinoid ADC technology to develop and commercialize products for a specified number of individual targets on terms agreed upon at the inception of the right-to-test agreement. The terms of the right-to-test agreement require Lilly to exercise its options for the development and commercialization licenses by the end of the term of the research license. In August 2013, Lilly took its first development and commercialization license to a single target.

The Company received a \$20 million upfront payment in connection with the execution of the right-to-test agreement, and for the first development and commercialization license taken in August 2013 and amended in December 2013, the Company received an exercise fee in the amount of \$2 million and is entitled to receive up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. Lilly has the right to elect, at its discretion, which of the two additional development and commercialization licenses it has a right to take under the right-to-test agreement will have no exercise fee and which will have an exercise fee of \$2 million. With respect to any subsequent development and commercialization license taken, if Lilly elects that the \$2 million exercise fee is payable, the Company is entitled to receive, in addition to the exercise fee, up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. If Lilly elects that no exercise fee is payable when it takes a development and commercialization license, the Company is entitled to receive up to a total of \$200.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$29 million for the development and commercialization licenses with respect to which the \$2 million exercise fee is paid, and \$30.5 million for the development and commercialization license with respect to which no exercise fee is payable; regulatory milestones \$70 million in all cases; and sales milestones \$100 million in all cases. The next payment the Company could receive would either be a \$5 million development milestone payment with the initiation of a Phase I clinical trial under the first development and commercialization license taken, or a \$2 million exercise fee for the execution of an additional license if Lilly elects to pay the exercise fee with respect to such license. At the time of execution of this agreement, there was significant uncertainty as to whether the milestone related to initiation of a Phase I clinical trial under the first development and commercialization license would be achieved. In consideration of this, as well as the Company's expected involvement in the research and manufacturing of these product candidates, this milestone was deemed substantive. The Company also is entitled to receive payments for delivery of cytotoxic agents to Lilly and research and development activities performed on behalf of Lilly. Lilly is responsible for the manufacturing, product development and marketing of any products resulting from this collaboration.

In accordance with ASC 605-25 (as amended by ASU No. 2009-13), the Company identified all of the deliverables at the inception of the right-to-test agreement. The significant deliverables were determined to be the right-to-test, or research, license, the exclusive development and commercialization licenses, rights to future technological improvements, delivery of cytotoxic agents and the research services. The options to obtain development and commercialization licenses in the right-to-test agreement were determined not to be substantive and, as a result, the exclusive development and commercialization licenses were considered deliverables at the inception of the right-to-test agreement. Factors that were considered in determining the options were not substantive included (i) the overall objective of the agreement was for Lilly to obtain development and commercialization licenses, (ii) the size of the exercise fees of \$2 million for each development and commercialization license taken beyond the first license is not significant relative to the \$20 million upfront payment that was due at the inception of the right-to-test agreement, (iii) the limited economic benefit that Lilly could obtain from the right-to-test agreement unless it exercised its options to obtain development and commercialization licenses, and (iv) the lack of economic penalties as a result of exercising the options.

The Company has determined that the research license together with the development and commercialization licenses represent one unit of accounting as the research license does not have stand-alone value from the development and commercialization licenses due to the lack of transferability of the research license and the limited economic benefit Lilly would derive if they did not obtain any development and commercialization licenses. The Company has also determined that this unit of accounting has stand-alone value from the rights to future technological improvements, the delivery of cytotoxic agents and the research services. The rights to future technological improvements, delivery of cytotoxic agents and the research services are considered separate units of accounting as each of these was determined to have stand-alone value. The rights to future technological improvements have stand-alone value as Lilly would be able to use those items for their intended purpose without the undelivered elements. The research services and cytotoxic agents have stand-alone value as similar services and products are sold separately by other vendors.

Table of Contents

The estimated selling prices for the development and commercialization licenses are the Company's best estimate of selling price and were determined based on market conditions, similar arrangements entered into by third parties, including pricing terms offered by our competitors for single-target development and commercialization licenses that utilize antibody-drug conjugate technology, and entity-specific factors such as the pricing terms of the Company's previous single-target development and commercialization licenses, recent preclinical and clinical testing results of therapeutic products that use the Company's ADC technology, and the Company's pricing practices and pricing objectives. The estimated selling price of the rights to technological improvements is the Company's best estimate of selling price and was determined by estimating the probability that technological improvements will be made, and the probability that technological improvements made will be used by Lilly. In estimating these probabilities, we considered factors such as the technology that is the subject of the development and commercialization licenses, our history of making technological improvements, and when such improvements, if any, were likely to occur relative to the stage of development of any product candidates pursuant to the development and commercialization licenses. The company's estimate of probability considered the likely period of time that any improvements would be utilized, which was estimated to be ten years following delivery of a commercialization and development license. The value of any technological improvements made available after this ten year period was considered to be *de minimis* due to the significant additional costs that would be incurred to incorporate such technology into any existing product candidates. The estimate of probability was multiplied by the estimated selling price of the development and commercialization licenses and the resulting cash flow was discounted at a rate of 16%, representing the Company's estimate of its cost of capital at the time. The estimated selling price of the cytotoxic agent was based on third-party evidence given market rates for the manufacture of such cytotoxic agents. The estimated selling price of the research services was based on third-party evidence given the nature of the research services to be performed for Lilly and market rates for similar services.

The total arrangement consideration of \$28.2 million (which comprises the \$20 million upfront payment, the exercise fee, if any, for each license, the expected fees for the research services to be provided and the cytotoxic agent to be delivered under the arrangement) was allocated to the deliverables based on the relative selling price method as follows: \$23.5 million to the development and commercialization licenses; \$0.6 million to the rights to future technological improvements, \$0.8 million to the sale of cytotoxic agent; and \$3.3 million to the research services. Upon execution of the development and commercialization license taken by Lilly in August 2013, the Company recorded \$7.8 million of the \$23.5 million of the arrangement consideration outlined above, which is included in license and milestone fee revenue for the three month period ended September 30, 2013. With this first development and commercialization license taken, the amount of the total arrangement consideration allocated to future technological improvements will commence to be recognized as revenue ratably over the period the Company is obligated to make available any technological improvements, which is the equivalent to the estimated term of the license. The Company estimates the term of a development and commercialization license to be approximately 25 years, which reflects management's estimate of the time necessary to develop and commercialize therapeutic products pursuant to the license plus the estimated royalty term. The Company will reassess the estimated term at each subsequent reporting period. The Company will recognize as license revenue an equal amount of the total remaining \$15.7 million of arrangement consideration allocated to the development and commercialization licenses as each individual license is delivered to Lilly upon Lilly's exercise of its remaining options to such licenses. The Company does not control when Lilly will exercise its options for development and commercialization licenses. As a result, the Company cannot predict when it will recognize the related license revenue except that it will be within the term of the research license. The Company will recognize research services revenue and revenue from the delivery of cytotoxic agents as the related services and cytotoxic agents are delivered.

For additional information related to these agreements, as well as the Company's other significant collaborative agreements, please read Note C, *Agreements* to our consolidated financial statements included within the Company's 2014 Form 10-K.

C. Capital Stock

2001 Non-Employee Director Stock Plan

Edgar Filing: IMMUNOGEN INC - Form 10-Q

During the three months ended September 30, 2014, the Company recorded approximately \$(8,000) in expense reduction related to stock units outstanding under the Company's 2001 Non-Employee Director Stock Plan, or the 2001 Plan, compared to \$3,000 in expense recorded during the three months ended September 30, 2013. The value of the stock units are classified as a liability and 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.

Compensation Policy for Non-Employee Directors

On November 12, 2013, the Board amended the Compensation Policy for Non-Employee Directors to make certain changes to the compensation of its non-employee directors, including an increase in the fees paid in cash to the non-employee directors. Under the terms of the amended policy, the redemption amount of deferred share units issued will continue to be paid in shares of common stock of the Company on the date a director ceases to be a member of the Board. Annual retainers vest quarterly over approximately

Table of Contents

one year from the date of grant, contingent upon the individual remaining a director of ImmunoGen as of each vesting date. The number of deferred share units awarded is now fixed per the plan on the date of the award and is no longer based on the market price of the Company's common stock on the date of the award. All unvested deferred stock awards will automatically vest immediately prior to the occurrence of a change of control.

In addition to the deferred share units, the Non-Employee Directors are now also entitled to receive a fixed number of stock options instead of a fixed grant date fair value of options, determined using the Black-Scholes option pricing model measured on the date of grant, which would be the date of the annual meeting of shareholders. These options vest quarterly over approximately one year from the date of grant. Any new directors will receive a pro-rated award, depending on their date of election to the Board. The directors received a total of 80,000 and 41,805 stock options in fiscal 2014 and 2013, respectively, and the related compensation expense for the three months ended September 30, 2014 and 2013 is included in the amounts discussed in the "Stock-Based Compensation" section of footnote A above.

During the three months ended September 30, 2014, the Company recorded approximately \$118,000 in compensation expense, respectively, related to deferred share units issued and outstanding under the Company's Compensation Policy for Non-Employee Directors, compared to \$98,000 in compensation expense recorded during the three months ended September 30, 2013.

D. Cash and Cash Equivalents

As of September 30, 2014 and June 30, 2014, the Company held \$121.8 million and \$142.3 million, respectively, in cash and money market funds consisting principally of U.S. Government-issued securities and high quality, short-term commercial paper which were classified as cash and cash equivalents.

E. Commitments and Contingencies

Leases

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 through March 2020. The Company uses this space for its corporate headquarters and other operations. In December 2013, the Company modified its lease agreement at 830 Winter Street, Waltham, MA to include approximately 19,000 square feet of additional office space through 2020, concurrent with the remainder of the original lease term. As part of the lease amendment, the Company will receive a construction allowance of approximately \$746,000 to build out office space to the Company's specifications. The Company obtained physical control of the additional space to begin construction in January 2014. In April, 2014, the Company again modified its lease agreement at this site to extend the lease to 2026. The Company may extend the lease for two additional terms of five years. As part of this lease amendment, the Company will receive a construction allowance of approximately \$1.1 million to build out office space to the Company's specifications. 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 sublease in December 2009 for 14,100 square feet of this space in Waltham through January 2015, with the sublessee having a conditional option to extend the term for an additional two years. However, the Company has notified the sublessee that it does not intend to allow them to extend the term beyond January 2015.

Edgar Filing: IMMUNOGEN INC - Form 10-Q

Effective April 2012, the Company entered into a sublease agreement for the rental of 7,310 square feet of laboratory and office space at 830 Winter Street, Waltham, MA from Histogenics Corporation. The term of the sublease is for three years and 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 also leases manufacturing and office space at 333 Providence Highway, Norwood, MA under an agreement through 2018 with an option to extend the lease for an additional term 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.

Effective April 2013, the Company entered into a lease agreement with River Ridge Limited Partnership for the rental of 7,507 square feet of additional office space at 100 River Ridge Drive, Norwood, MA. The initial term of the lease is for five years and two months commencing in July 2013 with an option for the Company to extend the lease for an additional term 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.

Table of Contents

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

2015 (nine months remaining)	\$	5,328
2016		6,908
2017		6,925
2018		7,031
2019		6,219
Thereafter		43,781
Total minimum lease payments	\$	76,192
Total minimum rental payments from sublease		(233)
Total minimum lease payments, net	\$	75,959

There are no obligations under capital leases as of September 30, 2014, as all of the capital leases were single payment obligations which have all been made.

Collaborations

The Company is contractually obligated to make potential future success-based development, regulatory or sales milestone payments in conjunction with certain collaborative agreements. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, the Company may be required to pay such amounts. Further, the timing of any future payment is not reasonably estimable. As of September 30, 2014, the maximum amount that may be payable in the future under the Company's current collaborative agreements is \$162 million, \$1.4 million of which is reimbursable by a third party under a separate agreement.

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, antibody-drug conjugates, or ADCs, for the treatment of cancer using our expertise in cancer biology, monoclonal antibodies, highly potent cytotoxic, or cell-killing, agents, and the design of linkers that enable these agents to remain stably attached to the antibodies while in the blood stream and released in their fully active form after delivery to a cancer cell. An anticancer compound made using our ADC technology consists of a monoclonal antibody that binds specifically to an antigen target found on the surface of cancer cells with one of our proprietary cell-killing agents attached to the antibody using one of our engineered linkers. Its antibody component enables an ADC compound to bind specifically to cancer cells that express its target antigen, the highly potent cytotoxic agent serves to kill the cancer cell, and the engineered linker controls the release and activation of the cytotoxic agent inside the cancer cell. With some ADC compounds, the antibody component also has anticancer activity of its own. Our ADC technology is designed to enable the creation of highly effective, well-tolerated anticancer products. All of the ADC compounds currently in clinical testing contain either DM1 or DM4 as the cytotoxic agent. Both DM1 and DM4, collectively DMx, are our proprietary derivatives of a cytotoxic agent called maytansine. We also have developed agents we call IGNs, one of which, DGN462, is used in our preclinical compound IMG779.

We use our proprietary ADC technology in conjunction with our in-house antibody expertise to develop our own anticancer product candidates. We also enter into agreements that enable companies to use our ADC technology to develop and commercialize product candidates to specified targets. Under the terms of our agreements, we are generally entitled to upfront fees, milestone payments, and royalties on any commercial product sales. In addition, under certain agreements we are compensated for research and development activities performed at our collaborative partner's request at negotiated prices which are generally consistent with what other third parties would charge. We are compensated to manufacture preclinical and clinical materials and deliver cytotoxic agent material at negotiated prices which are generally consistent with what other third parties would charge. Currently, our partners include Amgen, Bayer HealthCare, Biotest, Lilly, Novartis, Roche and Sanofi. We also have a research agreement with CytomX Therapeutics that allows each company to develop antibody-drug conjugates against a specified number of cancer targets using CytomX's Probody antibody masking technology with our payload agents and engineered linkers. We expect that substantially all of our revenue for the foreseeable future will result from payments under our collaborative arrangements. Details for all of our significant agreements can be found in our 2014 Annual Report on Form 10-K.

Table of Contents

Roche In May 2000, we granted Genentech, now a unit of Roche, an exclusive license to use our maytansinoid ADC technology with antibodies, such as trastuzumab, or other proteins that target HER2. Under the terms of this agreement, Roche has exclusive worldwide rights to develop and commercialize maytansinoid ADC compounds targeting HER2. In February 2013, the US FDA granted marketing approval to the HER2-targeting ADC compound, Kadcyla. Roche received marketing approval for Kadcyla in Japan and in the EU in September 2013 and November 2013, respectively, and with each event, we received a \$5 million regulatory milestone payment. Roche is responsible for the manufacturing, product development and marketing of Kadcyla and any other products resulting from the agreement. We received a \$2 million non-refundable upfront payment from Roche upon execution of the agreement. We are also entitled to receive up to a total of \$44 million in milestone payments, plus royalties on the commercial sales of Kadcyla and any other resulting products. Total milestones are categorized as follows: development milestones \$13.5 million; and regulatory milestones \$30.5 million. Through September 30, 2014, we have received and recognized \$13.5 million and \$20.5 million in development and regulatory milestone payments, respectively, related to Kadcyla. Included in license and milestone fees for the three months ended September 30, 2013 is a \$5 million milestone payment for marketing approval of Kadcyla in Japan.

We receive royalty reports and payments related to sales of Kadcyla from Roche one quarter in arrears. In accordance with our revenue recognition policy, \$4.2 million of royalties on net sales of Kadcyla for the three-month period ended June 30, 2014 were recorded and included in royalty revenue for the three months ended September 30, 2014 and \$2.1 million of royalties on net sales of Kadcyla for the three-month period ended June 30, 2013 is included in royalty revenue for the three months ended September 30, 2013.

Sanofi In July 2003, we entered into a broad collaboration agreement with Sanofi (formerly Aventis) to discover, develop and commercialize antibody-based products. The collaboration agreement provides Sanofi with worldwide development and commercialization rights to new antibody-based products directed to targets that are included in the collaboration, including the exclusive right to use our maytansinoid ADC technology in the creation of products developed to these targets. The product candidates (targets) as of September 30, 2014 in the collaboration include SAR3419 (CD19), SAR650984 (CD38), SAR566658 (CA6), SAR408701 (CEACAM5) and one earlier-stage compound that has yet to be disclosed.

We are entitled to receive milestone payments potentially totaling \$21.5 million, per target, payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$7.5 million; and regulatory milestones \$14 million. Through September 30, 2014, the Company has received and recognized an aggregate of \$20.5 million in milestone payments for compounds covered under this agreement now or in the past, including a \$3 million development milestone related to initiation of a Phase IIb clinical trial (as defined in the agreement) for SAR650984 and a \$1 million development milestone related to initiation of a Phase I clinical trial for SAR408701 which are included in license and milestone fee revenue for the three months ended September 30, 2014.

In December 2006, we entered into a right-to-test agreement with Sanofi. The agreement provides Sanofi with the right to (a) test our maytansinoid ADC technology with Sanofi's antibodies to targets under a right-to-test, or research, license, (b) take exclusive options, with certain restrictions, to specified targets for specified option periods and (c) upon exercise of those options, take exclusive licenses to use the Company's maytansinoid ADC technology to develop and commercialize products directed to the specified targets on terms agreed upon at the inception of the right-to-test agreement. For each development and commercialization license taken, we are entitled to receive an exercise fee of \$2 million and up to a total of \$30 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$10 million; and regulatory milestones \$20 million.

In December 2013, Sanofi took its first exclusive development and commercialization license under the right-to-test agreement, for which we received an exercise fee of \$2 million and was recognizing this amount as revenue ratably over our estimated period of its substantial involvement. We had previously estimated this development period would conclude at the end of non-pivotal Phase II testing. During the current quarter, we determined it will not be substantially involved in the development and commercialization of the product based on Sanofi's

Edgar Filing: IMMUNOGEN INC - Form 10-Q

current plans to develop and manufacture the product without our assistance. As a result of this determination, we recognized the balance of the upfront exercise fee during the current quarter. This change in estimate results in an increase to license and milestone fees of \$1.7 million for the three months ended September 30, 2014 compared to amounts that would have been recognized pursuant to our previous estimate.

Lilly In December 2011, we entered into a three-year right-to-test agreement with Lilly. The agreement provides Lilly with the right to (a) take exclusive options, with certain restrictions, to individual targets selected by Lilly for specified option periods, (b) test our maytansinoid ADC technology with Lilly's antibodies directed to the optioned targets under a right-to-test, or research, license, and (c) upon exercise of those options, take exclusive licenses to use our maytansinoid ADC technology to develop and commercialize products for a specified number of individual targets on terms agreed upon at the inception of the right-to-test agreement. The terms of the right-to-test agreement require Lilly to exercise its options for the development and commercialization

Table of Contents

licenses by the end of the term of the research license. In August 2013, Lilly took its first development and commercialization license to a single target.

We received a \$20 million upfront payment in connection with the execution of the right-to-test agreement. In December 2013, we and Lilly amended the right-to-test agreement and the first development and commercialization license. Under these amendments, Lilly now has the right to extend the three-year research period under the right-to-test agreement for up to two nine-month periods by payment to us of additional consideration prior to the expiration of both the original term or the first extended term of that agreement. In addition, Lilly retroactively paid us an exercise fee of \$2 million for the first development and commercialization license, and has the right to elect, at its discretion, which of the two additional development and commercialization licenses it has a right to take under the right-to-test agreement will have no exercise fee and which will have an exercise fee of \$2 million. The application of the \$2 million exercise fee to the first license granted under the arrangement did not impact the total arrangement consideration, only the timing of payment of the consideration. For the first development and commercialization license taken, which occurred in August 2013, we are entitled to receive up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. With respect to any subsequent development and commercialization license taken, if Lilly elects that the \$2 million exercise fee is payable, we are entitled to receive, in addition to the exercise fee, up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. If Lilly elects that no exercise fee is payable when it takes a subsequent development and commercialization license, we are entitled to receive up to a total of 200.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$29 million for the development and commercialization licenses with respect to which the \$2 million exercise fee is paid, and \$30.5 million for the development and commercialization license with respect to which no exercise fee is payable; regulatory milestones \$70 million in all cases; and sales milestones \$100 million in all cases. In accordance with our revenue recognition policy, upon execution of the development and commercialization license taken by Lilly in August 2013, we recorded \$7.8 million of revenue which is included in license and milestone fee revenue for the three months ended September 30, 2013.

To date, we have not generated revenues from commercial sales of internal products and we expect to incur significant operating losses for the foreseeable future. As of September 30, 2014, we had approximately \$121.8 million in cash and cash equivalents compared to \$142.3 million in cash and cash equivalents as of June 30, 2014.

We anticipate that future cash expenditures will be partially offset by collaboration-derived proceeds, including milestone payments, royalties 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 secure alternative financing arrangements, find additional partners 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 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, clinical trial accruals, inventory and stock-based compensation. 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.

There were no significant changes to our critical accounting policies from those disclosed in our Annual Report on Form 10-K for the fiscal year ended June 30, 2014.

Table of Contents**RESULTS OF OPERATIONS***Comparison of Three Months ended September 30, 2014 and 2013**Revenues*

Our total revenues for the three months ended September 30, 2014 and 2013 were \$13.2 million and \$17.2 million, respectively. The \$4.0 million decrease in revenues in the three months ended September 30, 2014 from the same period in the prior year is attributable to a decrease in license and milestone fees and research and development support revenue, partially offset by an increase in royalty revenue and clinical materials revenue, all of which are discussed below.

Revenues from license and milestone fees for the three months ended September 30, 2014 decreased \$7.0 million to \$6.2 million from \$13.2 million in the same period ended September 30, 2013. Included in license and milestone fees for the three months ended September 30, 2014 is \$4 million in development milestones achieved under our collaboration agreement with Sanofi. Also, during the current quarter, we made a change in estimate to our period of substantial involvement as it relates to an exclusive license with Sanofi which resulted in an increase to license and milestone fees of \$1.7 million for the current quarter compared to amounts that would have been recognized pursuant to the Company's previous estimate. Included in license and milestone fees for the three months ended September 30, 2013 is a \$5 million regulatory milestone achieved under our collaboration agreement with Roche and \$7.8 million of license fee revenue earned upon the execution of a development and commercialization license by Lilly. The amount of license and milestone fees we earn is directly related to the number of our collaborators, the collaborators' advancement of the product candidates, and the overall success in the clinical trials of the product candidates. As such, the amount of license and milestone fees may vary significantly from quarter to quarter and year to year. Total revenue from license and milestone fees recognized from each of our collaborative partners in the three-month periods ended September 30, 2014 and 2013 is included in the following table (in thousands):

License and Milestone Fees Collaborative Partner:	Three Months Ended September 30,	
	2014	2013
Amgen	\$ 4	\$ 115
Biotest	6	6
Janssen	241	
Lilly	6	7,813
Novartis	45	41
Sanofi	5,932	192
Roche		5,000
Total	\$ 6,234	\$ 13,167

Deferred revenue of \$58.4 million as of September 30, 2014 primarily represents consideration received from our collaborators pursuant to our license agreements, which we have yet to earn pursuant to our revenue recognition policy. Included within this amount is \$13 million of non-cash consideration recorded in connection with our arrangement with CytomX.

Edgar Filing: IMMUNOGEN INC - Form 10-Q

In February 2013, the U.S. FDA granted marketing approval to Kadcyła, a product resulting from one of our development and commercialization licenses with Roche, through its Genentech unit. We receive royalty reports and payments related to sales of Kadcyła from Roche one quarter in arrears. In accordance with our revenue recognition policy, \$4.2 million of royalties on net sales of Kadcyła for the three-month period ended June 30, 2014 were recorded and included in royalty revenue for the three months ended September 30, 2014 and \$2.1 million of royalties on net sales of Kadcyła for the three-month period ended June 30, 2013 is included in royalty revenue for the three months ended September 30, 2013. We expect royalty revenue to increase in future periods as the underlying net sales of Kadcyła increase.

Research and development support revenue was \$776,000 for the three months ended September 30, 2014 compared with \$2 million for the three months ended September 30, 2013. These amounts primarily represent research funding earned based on actual resources utilized under our agreements with our collaborators shown in the table below. Also included in research and development support revenue are fees for 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 research and development support revenue 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 research and development support revenue may vary widely from quarter to quarter and year to year. Total revenue recognized from

Table of Contents

research and development support from each of our collaborative partners in the three-month periods ended September 30, 2014 and 2013 is included in the following table (in thousands):

Research and Development Support Collaborative Partner:	Three Months Ended September 30,	
	2014	2013
Amgen	\$ 19	\$ 66
Biotest	110	239
Lilly	409	528
Novartis	197	1,155
Other	41	2
Total	\$ 776	\$ 1,990

Clinical materials revenue was \$2 million for the three months ended September 30, 2014 compared with \$8,000 for the three months ended September 30, 2013. We are compensated at negotiated prices which are generally consistent with what other third-parties would charge. The amount of clinical materials revenue 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 who use us to manufacture clinical materials 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 demand our collaborators have for clinical-grade material for process development and analytical purposes. As such, the amount of clinical materials 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 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 which also includes raw materials.

Research and development expense for the three months ended September 30, 2014 increased \$6 million to \$28 million from \$22 million for the three months ended September, 2013. Salaries and related expenses increased due to additional headcount, increased incentive compensation and increased stock compensation costs. The number of our research and development personnel increased to 265 as of September 30, 2014 compared to 247 at September 30, 2013. The higher stock compensation is driven by higher stock prices and increases in the number of options granted due to increases in personnel. Facility-related expenses increased due primarily to additional laboratory and office space occupied in July 2014 and increased depreciation and amortization related to major capital equipment and improvements. A more detailed discussion of research and development expense in the period follows.

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.

Edgar Filing: IMMUNOGEN INC - Form 10-Q

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, 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 impractical 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

Table of Contents

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 September 30,	
	2014	2013
Research	\$ 4,988	\$ 4,558
Preclinical and Clinical Testing	10,192	8,612
Process and Product Development	2,254	2,038
Manufacturing Operations	10,584	6,821
Total Research and Development Expense	\$ 28,018	\$ 22,029

Research: Research includes expenses primarily 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, contract services, research licensing fees, facilities and lab supplies. Research expenses for the three months ended September 30, 2014 increased \$430,000 compared to the three months ended September 30, 2013. This increase is primarily the result of an increase in salaries and related expenses and an increase in facility-related expenses. We expect research expenses for fiscal 2015 to be significantly lower than fiscal 2014 due to the \$12.8 million non-cash charge recorded for technology rights obtained under the collaboration agreement executed with CytomX in fiscal 2014. No similar charges are expected to be incurred during fiscal 2015.

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, regulatory activities, 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 September 30, 2014 increased \$1.6 million to \$10.2 million compared to \$8.6 million for the three months ended September 30, 2013. This increase is primarily the result of higher salaries and related expenses, an increase in facility-related expenses, and an increase in contract service expense driven primarily by increased study activities related to IMG853 and IMG289. Partially offsetting these increases, clinical trial costs decreased in the current period due to the termination of the IMG901 007 Phase II study in November 2013. We expect preclinical and clinical testing expenses for fiscal 2015 to be significantly higher than fiscal 2014 due to increased activities to advance our wholly owned product candidates.

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 September 30, 2014, total development expenses increased \$216,000 compared to the three months ended September 30, 2013. This increase is primarily the result of an increase in salaries and related expenses and facility-related expenses. We expect process and product development expenses for fiscal 2015 to be marginally higher than fiscal 2014.

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

Edgar Filing: IMMUNOGEN INC - Form 10-Q

clinical trials, development costs with contract manufacturing organizations, manufacturing supplies, and facilities expense. For the three months ended September 30, 2014, manufacturing operations expense increased \$3.8 million to \$10.6 million compared to \$6.8 million in the same period last year. The increase in the three months ended September 30, 2014 as compared to the three months ended September 30, 2013 is primarily the result of (i) an increase in cost of clinical materials revenue charged to research and development expense due to timing of orders of such clinical materials from our partners; (ii) an increase in contract service expense driven by increased development activities related to our cytotoxic agents and developing third-party conjugation capabilities for our internal products; and (iii) an increase in salaries and related expenses. Partially offsetting these increases, costs capitalized into inventory increased due to a greater number of manufactured batches of conjugated materials on behalf of our collaborators during the current period. We expect manufacturing operations expense for fiscal 2015 to be significantly higher than fiscal 2014 due primarily to increased activities to advance our wholly owned product candidates.

Table of Contents*General and Administrative Expenses*

General and administrative expenses for the three months ended September 30, 2014 increased \$569,000 to \$7.1 million compared to \$6.5 million in the same period last year. This increase is primarily due to an increase in salaries and related expenses, as well as an increase in patent expenses. We expect general and administrative expenses for fiscal 2015 to be higher than fiscal 2014 due primarily to increased salaries and related expenses, patent activities and other professional services.

Other (Expense) Income, net

Other (expense) income, net for the three months ended September 30, 2014 and 2013 is included in the following table (in thousands):

Other (Expense) Income, net	Three Months Ended September 30,	
	2014	2013
Interest Income	\$ 8	\$ 11
Other (Expense) Income, net	(380)	100
Total Other (Expense) Income, net	\$ (372)	\$ 111

The change in other (expense) income, net is primarily due to an increase in foreign currency exchange losses related to obligations with non-U.S. dollar-based suppliers and euros held by the Company to manage the foreign currency exposures related to these obligations. We incurred \$(381,000) and \$97,000 in foreign currency exchange (losses) and gains during the three months ended September 30, 2014 and 2013, respectively.

LIQUIDITY AND CAPITAL RESOURCES

	As of	
	September 30, 2014	June 30, 2014
	(In thousands)	
Cash and cash equivalents	\$ 121,798	\$ 142,261
Working capital	88,556	129,502
Shareholders' equity	58,971	75,699

	Three Months Ended September 30,	
	2014	2013
	(In thousands)	
Cash used for operating activities	\$ (18,899)	\$ (23,575)
Cash used for investing activities	(1,708)	(572)
Cash provided by financing activities	144	4,025

Cash Flows

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 license fees, milestones, research funding and more recently, royalties. As of September 30, 2014, we had approximately \$121.8 million in cash and cash equivalents. Net cash used for operations was \$18.9 million and \$23.6 million for the three months ended September 30, 2014 and 2013, respectively. The principal use of cash for operating activities for both periods presented was to fund our net loss.

Net cash used for investing activities was \$1.7 million and \$572,000 for the three months ended September 30, 2014 and 2013, respectively, and represents cash outflows for capital expenditures, primarily for the purchase of new equipment and leasehold improvements.

Net cash provided by financing activities was \$144,000 and \$4 million for the three months ended September 30, 2014 and 2013, respectively, which represents proceeds from the exercise of approximately 25,000 and 545,000 stock options, respectively.

We anticipate that our current capital resources and expected future collaborator payments under existing collaborations will enable us to meet our operational expenses and capital expenditures partway through fiscal year 2016. However, we cannot provide assurance that such future collaborative agreement funding will, in fact, be received. Should we or our partners not meet some or all of

Table of Contents

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

There have been no material changes to our contractual obligations during the current period from those disclosed in our Annual Report on Form 10-K for the fiscal year ended June 30, 2014.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update 2014-9, *Revenue from Contracts with Customers (Topic 606)*, to clarify the principles for recognizing revenue. This update provides a comprehensive new revenue recognition model that requires revenue to be recognized in a manner to depict the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, and allows for either full retrospective or modified retrospective application, with early adoption not permitted. Accordingly, the standard is effective for us on July 1, 2017. We are currently evaluating the adoption method we will apply and the impact that this guidance will have on our financial statements and related disclosures.

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. These statements also relate to our future prospects, developments and business strategies.

These forward-looking statements can be identified by their use of terms and phrases, such as anticipate, believe, could, estimate, expect, in, may, plan, predict, project, will and other similar terms and phrases, including references to assumptions. They may also use words such as would, should, could or may. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from those contemplated by our forward-looking statements. These known and unknown risks, uncertainties and other factors are described in detail in the Risk Factors section and in other sections of this Annual Report on Form 10-K for the year ended June 30, 2014. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Kadcyla® is a registered trademark of Genentech, Inc., a member of the Roche Group.

Probody is a trademark of CytomX Therapeutics, Inc.

OFF-BALANCE SHEET ARRANGEMENTS

None.

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

Our market risks, and the ways we manage them, are summarized in Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* of our Annual Report on Form 10-K for the fiscal year ended June 30, 2014. Since then there have been no material changes to our market risks or to our management of such risks.

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

Table of Contents

(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 September 30, 2014 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

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, 2014. There have been no material changes from the factors disclosed in our 2014 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.

Table of Contents

ITEM 6. Exhibits

Exhibit No.	Description
10.1	Employment offer letter between the Registrant and Sandra Poole
10.2	Change in Control Severance Agreement dated as of September 15, 2014 between the Registrant and Sandra Poole
10.3	Summary of Annual Bonus Program
10.4	Amendment No. 1, dated as of August 31, 2006, to the Collaboration and License Agreement between the Registrant and sanofi-aventis U.S. LLC
10.5	Amendment No. 2, dated as of December 7, 2007, to the Collaboration and License Agreement between the Registrant and sanofi-aventis U.S. LLC
10.6	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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

Furnished, not filed.

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: October 30, 2014

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

Date: October 30, 2014

By: /s/ David B. Johnston
David B. Johnston
Executive Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)