

IMMUNOGEN INC  
Form 10-Q  
February 05, 2014  
[Table of Contents](#)

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

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended December 31, 2013

OR

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

For the transition period from            to

Commission file number 0-17999

**ImmunoGen, Inc.**

Edgar Filing: IMMUNOGEN INC - Form 10-Q

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

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

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

(Address of principal executive offices, including zip code)

**(781) 895-0600**

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant 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

Smaller reporting company

(Do not check if a 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: 85,672,716 shares outstanding as of January 27, 2014.

Table of Contents

IMMUNOGEN, INC.

FORM 10-Q

FOR THE QUARTER ENDED DECEMBER 31, 2013

TABLE OF CONTENTS

Item	Page Number
<b>Part I</b>	
<u>1. Financial Statements (Unaudited):</u>	
<u>1a. Consolidated Balance Sheets as of December 31, 2013 and June 30, 2013</u>	3
<u>1b. Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and six months ended December 31, 2013 and 2012</u>	4
<u>1c. Consolidated Statements of Cash Flows for the six months ended December 31, 2013 and 2012</u>	5
<u>1d. Notes to Consolidated Financial Statements</u>	6
<u>2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>3. Quantitative and Qualitative Disclosures about Market Risk</u>	31
<u>4. Controls and Procedures</u>	31
<b>Part II</b>	
<u>1A. Risk Factors</u>	32
<u>6. Exhibits</u>	32
<u>Signatures</u>	33

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

	<b>December 31, 2013</b>	<b>June 30, 2013</b>
<b>ASSETS</b>		
Cash and cash equivalents	\$ 178,088	\$ 194,960
Accounts receivable	3,818	
Unbilled revenue	1,904	2,121
Inventory	3,008	703
Restricted cash	319	319
Prepaid and other current assets	2,321	2,581
Total current assets	189,458	200,684
Property and equipment, net of accumulated depreciation	10,753	10,783
Long-term restricted cash	1,912	1,912
Other assets	400	217
Total assets	\$ 202,523	\$ 213,596
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Accounts payable	\$ 3,812	\$ 4,498
Accrued compensation	4,162	6,153
Other accrued liabilities	6,158	6,049
Current portion of deferred lease incentive	979	979
Current portion of deferred revenue	2,522	1,494
Total current liabilities	17,633	19,173
Deferred lease incentive, net of current portion	5,137	5,626
Deferred revenue, net of current portion	46,487	63,384
Other long-term liabilities	3,230	3,566
Total liabilities	72,487	91,749
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 85,629 and 84,725 shares as of December 31, 2013 and June 30, 2013, respectively	856	847
Additional paid-in capital	713,361	697,767
Accumulated deficit	(584,181)	(576,767)
Total shareholders' equity	130,036	121,847
Total liabilities and shareholders' equity	\$ 202,523	\$ 213,596

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



Table of Contents

## IMMUNOGEN, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(UNAUDITED)

In thousands, except per share amounts

	Three Months Ended December 31,		Six Months Ended December 31,	
	2013	2012	2013	2012
<b>Revenues:</b>				
License and milestone fees	\$ 25,678	\$ 429	\$ 38,845	\$ 1,362
Royalty revenue	2,335		4,388	
Research and development support	1,922	2,036	3,912	3,413
Clinical materials revenue	125	147	133	1,928
<b>Total revenues</b>	<b>30,060</b>	<b>2,612</b>	<b>47,278</b>	<b>6,703</b>
<b>Operating Expenses:</b>				
Research and development	20,862	21,656	42,891	45,356
General and administrative	5,447	5,464	11,973	11,103
<b>Total operating expenses</b>	<b>26,309</b>	<b>27,120</b>	<b>54,864</b>	<b>56,459</b>
<b>Income (loss) from operations</b>	<b>3,751</b>	<b>(24,508)</b>	<b>(7,586)</b>	<b>(49,756)</b>
<b>Other income, net</b>	<b>62</b>	<b>115</b>	<b>172</b>	<b>171</b>
<b>Net income (loss)</b>	<b>\$ 3,813</b>	<b>\$ (24,393)</b>	<b>\$ (7,414)</b>	<b>\$ (49,585)</b>
<b>Basic and diluted net income (loss) per common share</b>	<b>\$ 0.04</b>	<b>\$ (0.29)</b>	<b>\$ (0.09)</b>	<b>\$ (0.59)</b>
<b>Basic weighted average common shares</b>				
outstanding	85,431	84,147	85,221	83,748
Dilutive impact of potential common shares	1,845			
<b>Diluted weighted average common shares</b>	<b>87,276</b>	<b>84,147</b>	<b>85,221</b>	<b>83,748</b>
<b>Total comprehensive income (loss)</b>	<b>\$ 3,813</b>	<b>\$ (24,393)</b>	<b>\$ (7,414)</b>	<b>\$ (49,585)</b>

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

Table of Contents

## IMMUNOGEN, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

In thousands, except per share amounts

	Six Months ended December 31,	
	2013	2012
Cash flows from operating activities:		
Net loss	\$ (7,414)	\$ (49,585)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	2,307	2,336
Loss (gain) on sale/disposal of fixed assets	20	(17)
Gain on forward contracts	(2)	(163)
Stock and deferred share unit compensation	8,548	6,848
Deferred rent	(37)	(54)
Changes in operating assets and liabilities:		
Accounts receivable	(3,818)	(1,157)
Unbilled revenue	217	(810)
Inventory	(2,305)	838
Prepaid and other current assets	260	480
Other assets	(183)	(22)
Accounts payable	(686)	1,311
Accrued compensation	(1,991)	(1,769)
Other accrued liabilities	(676)	(503)
Deferred revenue	(15,869)	(442)
Net cash used for operating activities	(21,629)	(42,709)
Cash flows from investing activities:		
Purchases of property and equipment, net	(2,297)	(2,038)
Payments from settlement of forward contracts	(1)	(12)
Net cash used for investing activities	(2,298)	(2,050)
Cash flows from financing activities:		
Proceeds from common stock issuance, net		93,991
Proceeds from stock options exercised	7,055	851
Net cash provided by financing activities	7,055	94,842
Net change in cash and cash equivalents	(16,872)	50,083
Cash and cash equivalents, beginning balance	194,960	160,938
Cash and cash equivalents, ending balance	\$ 178,088	\$ 211,021

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





Table of Contents

**IMMUNOGEN, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2013**

**A. Summary of Significant Accounting Policies**

*Basis of Presentation*

The accompanying unaudited consolidated financial statements at December 31, 2013 and June 30, 2013 and for the three and six months ended December 31, 2013 and 2012 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, 2013.

*Subsequent Events*

The Company has evaluated all events or transactions that occurred after December 31, 2013 up through the date the Company issued these financial statements. In January 2014, the Company entered into a collaboration agreement with CytomX Therapeutics, Inc. (CytomX). Under the terms of the agreement, the companies will collaborate to each develop Probody<sup>®</sup>-drug conjugate (PDC) therapies against a defined number of targets using CytomX Probody<sup>®</sup> technology and ImmunoGen's antibody-drug conjugate, or ADC, technology. Each company retains full development control of PDC compounds resulting from its target selection and is responsible for preclinical and clinical testing, manufacturing, and commercialization of its own compounds. Under the terms of the agreement, there were no upfront payments made by the Company or CytomX. Each company is entitled to potentially receive from the other company clinical and post-approval milestone payments as well as royalties on the sales of any marketed products developed by the other company resulting from this collaboration. 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 ADC technology, (ii) rights to future technological improvements, (iii) research activities to be performed on behalf

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

of the collaborative partner, (iv) delivery of cytotoxic agents and (v) the manufacture of preclinical or clinical 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 whether 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 December 31, 2013, 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):

Amgen (four exclusive single-target licenses)

Bayer HealthCare (one exclusive single-target license)

Table of Contents

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)

- Option/research 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

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 Kadcyła®, however, the minimum royalty term is 10 years and the maximum royalty term is 12 years on a country-by-country basis. Royalty rates may vary over the royalty term depending on the Company's intellectual property rights. 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 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, the likelihood that technological improvements 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

Table of Contents

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 be below its contract selling prices for its existing collaborations for the foreseeable future. During the six months ended December 31, 2012, 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 manufacture of preclinical and clinical materials was \$755,000. There were no sales of manufactured preclinical or clinical materials during the six months ended December 31, 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 for which the Company and its collaborators are preparing 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.

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

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 first moves into clinical testing or advances into different

Table of Contents

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 licensee's net sales of covered products. Generally, under these agreements the Company is to receive royalty reports and payments from its licensee's net sales of covered products. Generally, under these agreements the Company is to receive royalty reports and payments from its licensee's net sales of covered products 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 licensee's net sales of covered products, or one quarter following the quarter in which sales by the Company's licensee's net sales of covered products 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 options, for a defined period of time, to specified targets and (c) upon exercise of those options, secure or take licenses 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.

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,



Table of Contents

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

As of December 31, 2013, 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 December 31, 2013 (in thousands):

Edgar Filing: IMMUNOGEN INC - Form 10-Q

	Fair Value Measurements at December 31, 2013 Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash, cash equivalents and restricted cash	\$ 180,319	\$ 180,319	\$	\$

As of June 30, 2013, 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, 2013 (in thousands):

	Fair Value Measurements at June 30, 2013 Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash, cash equivalents and restricted cash	\$ 197,191	\$ 197,191	\$	\$

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

Table of Contents*Unbilled Revenue*

The majority of the Company's unbilled revenue at December 31, 2013 and June 30, 2013 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 December 31, 2013 and June 30, 2013 is summarized below (in thousands):

	<b>December 31, 2013</b>	<b>June 30, 2013</b>
Raw materials	\$ 474	\$ 75
Work in process	2,534	628
Total	\$ 3,008	\$ 703

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 \$205,000 and \$798,000 of expense related to excess inventory during the six-month periods ended December 31, 2013, and December 31, 2012, respectively. The Company recorded \$70,000 and \$408,000 of expense related to excess inventory during the three-month periods ended December 31, 2013 and December 31, 2012, 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 Income (Loss) per Common Share*

Basic and diluted net income (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

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

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 income (loss) 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):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2013	2012	2013	2012
Options outstanding to purchase common stock and unvested restricted stock	8,616	8,157	8,616	8,157
Common stock equivalents under treasury stock method	1,845	2,149	2,027	2,387

Potentially dilutive securities representing 3.2 million shares of common stock for the three-month period ended December 31, 2013, were excluded from the computation of diluted earnings per share because their effect would have been anti-dilutive. The Company's common stock equivalents have not been included in any net loss per share calculation because their effect is anti-dilutive due to the Company's net loss position.

Table of Contents*Stock-Based Compensation*

As of December 31, 2013, 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 any shares of common stock that are represented by awards granted under the previous stock option plan, the ImmunoGen, Inc. Restated Stock Option Plan, or the Former Plan, that are forfeited, expire or are cancelled without delivery of shares of common stock; provided, however, that no more than 5,900,000 shares shall be added to the 2006 Plan from the Former Plan, pursuant to this provision. Option awards are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Options vest at various periods of up to four years and may be exercised within ten years of the date of grant.

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 December 31,		Six Months Ended December 31,	
	2013	2012	2013	2012
Dividend	None	None	None	None
Volatility	60.44%	60.44%	60.44%	60.44%
Risk-free interest rate	1.92%	0.93%	1.72%	0.85%
Expected life (years)	6.3	6.3	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 December 31, 2013 and 2012 were \$8.76 and \$6.81 per share, respectively, and \$10.64 and \$8.60 per share for options granted during the six months ended December 31, 2013 and 2012, respectively.

Stock compensation expense related to stock options and restricted stock awards granted under the 2006 Plan was \$3.7 million and \$8.4 million during the three and six months ended December 31, 2013, respectively, compared to stock compensation expense of \$2.9 million and \$6.7 million for the three and six months ended December 31, 2012, respectively. As of December 31, 2013, the estimated fair value of unvested employee awards was \$27.2 million, net of estimated forfeitures. The weighted-average remaining vesting period for these awards is approximately two and a quarter years.

During the six months ended December 31, 2013, holders of options issued under the Company's equity plans exercised their rights to acquire an aggregate of approximately 861,000 shares of common stock at prices ranging from \$3.19 to \$15.83 per share. The total proceeds to the

Company from these option exercises were approximately \$7.1 million.

*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.

Table of Contents*Segment Information*

During the six months ended December 31, 2013, the Company continued to operate in one reportable business 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 and six months ended December 31, 2013 and 2012 are included in the following table:

<b>Collaborative Partner:</b>	<b>Three Months Ended December 31,</b>		<b>Six Months Ended December 31,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Amgen	9%	15%	6%	20%
Bayer HealthCare	%	%	%	12%
Biotest	1%	13%	1%	19%
Lilly	2%	8%	19%	7%
Novartis	64%	58%	43%	37%
Roche	24%	%	30%	%

There were no other customers of the Company with significant revenues in the three and six months ended December 31, 2013 and 2012.

*Recent Accounting Pronouncements*

In July 2013, the FASB issued guidance to address the diversity in practice related to the financial statement presentation of unrecognized tax benefits as either a reduction of a deferred tax asset or a liability when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. This guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

**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

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

(EU) in September 2013 and November 2013, respectively. 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. The Company received two \$5 million regulatory milestone payments in connection with marketing approval of Kadcyla in Japan and in the EU. Based on an evaluation of the effort contributed to the achievement of these milestones, the Company determined these milestones were 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 \$10 million non-refundable payments as revenue upon achievement of the milestones, which is included in license and milestone fees for the six months ended December 31, 2013, \$5 million of which is included in license and milestone fees for the three months ended December 31, 2013. Through December 31, 2013, the Company has received and recognized \$13.5 million and \$20.5 million in development and regulatory milestone payments, respectively, related to Kadcyla. The next potential milestone the Company will be entitled to receive will be a \$5 million regulatory milestone for marketing approval of Kadcyla for a first extended indication as defined in the agreement. Based on an evaluation of the effort contributed to the achievement of this milestone, the Company has determined this milestone is not substantive.

The Company receives royalty reports and payments related to sales of Kadcyla from Roche one quarter in arrears. In accordance with the Company's revenue recognition policy, \$2.3 million of royalties on net sales of Kadcyla for the three-month



Table of Contents

period ended September 30, 2013 were recorded and included in royalty revenue for the three months ended December 31, 2013 and \$4.4 million of royalties on net sales of Kadcyra for the six-month period ended September 30, 2013 is included in royalty revenue for the six months ended December 31, 2013. No such royalties were recorded in the prior year period.

*Amgen*

Under a now-expired right-to-test agreement entered into with Abgenix (now Amgen) in December 2000, in September 2009, November 2009 and December 2012, Amgen took three exclusive development and commercialization licenses, for which the Company received an exercise fee of \$1 million for each license taken. Under the same now-expired right-to-test agreement, in May 2013, Amgen took one non-exclusive development and commercialization license, for which the Company received an exercise fee of \$500,000. In October 2013, the non-exclusive license was amended and converted to an exclusive license, for which Amgen paid an additional \$500,000 fee to the Company. For each of these development and commercialization licenses, the Company is entitled to receive up to a total of \$34 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones per development and commercialization license are categorized as follows: development milestones \$9 million; regulatory milestones \$20 million; and sales milestones \$5 million. Amgen is responsible for the manufacturing, product development and marketing of any products resulting from the agreement. Amgen no longer has the right to take additional development and commercialization licenses under the agreement.

Since a deliverable to the original right-to-test agreement was determined to be materially modified at the time the non-exclusive license was converted to exclusive in October 2013, the Company accounted for the multiple-element agreement in accordance with ACS 605-25 (as amended by ASU No. 2009-13). As a result, all of the deferred revenue recorded on the date of the modification and the new consideration received as part of the modification was allocated to all of the remaining deliverables at the time of amendment of the right-to-test agreement based on the estimated selling price of each element. The remaining amount represents consideration for previously delivered elements and was recognized upon the execution of the modification.

The outstanding licenses, including the exclusive license delivered upon the signing of the amendment, contain the rights to future technological improvements as well as options to purchase materials and research and development services. The Company concluded that additional materials and research and development services would be paid at a contractual price equal to the estimated selling price based estimated prices that would be charged by third parties for similar services. The estimated selling price of the right 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 such technological improvements made will be used by Amgen. 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 13%, representing the Company's estimate of its cost of capital at the time of amendment of the right-to-test agreement.

The \$430,000 determined to be the estimated selling price of the future technological improvements is being recognized as revenue ratably over the period the Company is obligated to make available any technological improvements, which is equivalent to the estimated term of the agreement. 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 products pursuant to the license plus the estimated royalty term. The Company reassesses the estimated term at the end of each reporting period.

After accounting for the undelivered elements at the estimated selling price, the Company had \$2.2 million of remaining allocable consideration which was determined to represent consideration for the previously delivered elements, including the exclusive license that was delivered upon the execution of the modification. This amount was recorded as revenue and is included in license and milestone fees for the three and six months ended December 31, 2013.

The next potential milestone the Company will be entitled to receive under the December 2009 and November 2009 development and commercialization licenses will be a development milestone for the first dosing of a patient in a Phase II clinical trial, which will result in a \$3 million payment being due. The next potential milestones the Company will be entitled to receive under the December 2012 and May 2013 development and commercialization licenses will be a development milestone for IND approval which will result in a \$1 million payment being due to the Company. At the time of execution of each of these development and commercialization licenses, there was significant uncertainty as to whether these milestones would be achieved. In consideration of

Table of Contents

this, as well as the Company's past involvement in the research and manufacturing of these product candidates, these milestones were deemed substantive.

*Sanofi*

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. 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. 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. The Company has deferred the exercise fee and is recognizing the \$2 million as revenue ratably over the Company's estimated period of its substantial involvement. 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 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. Sanofi is responsible for the manufacturing, product development and marketing of any products resulting from the agreement.

In addition to the \$2 million exercise fee received for the development and commercialization license taken, the Company received upfront payments of \$4 million under the right-to-test agreement, of which \$500,000 was received in December 2006 upon execution of the agreement and \$3.5 million was received in August 2008 upon Sanofi's activation of its rights under the agreement. The right-to-test agreement had a three-year original term from the activation date and was renewed by Sanofi in August 2011 for its final three-year term by payment of a \$2 million fee. The Company has deferred the \$2 million extension fee and is recognizing this amount as revenue over the period during which Sanofi can take additional options for development and commercialization licenses.

*Novartis*

In October 2010, the Company entered into a three-year right-to-test agreement with Novartis Institutes for BioMedical Research, Inc. (Novartis). The agreement provides Novartis with the right to (a) test the Company's ADC technology with individual antibodies selected by Novartis under a right-to-test, or research, license, (b) take exclusive options, with certain restrictions, to individual targets selected by Novartis for specified option periods and (c) upon exercise of those options, take exclusive licenses to use the Company's 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 initial three-year term of the right-to-test agreement was extended by Novartis in October 2013 for an additional one-year period by payment of a \$5 million fee to the Company. In addition to the one-year extension taken in October 2013, the terms of the right-to-test agreement allow Novartis to extend the research term for one additional one-year period by payment of additional consideration. The terms of the right-to-test agreement require Novartis to exercise its options for the development and commercialization licenses by the end of the term of the research license. The Company received a \$45 million upfront payment in connection with the execution of the right-to-test agreement, and for each development and commercialization license for a specific target, the Company is entitled to receive an exercise fee of \$1 million and up to a total of \$199.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$22.5 million; regulatory milestones \$77 million; and sales milestones \$100 million. The

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

Company also is entitled to receive payments for research and development activities performed on behalf of Novartis. Novartis is responsible for the manufacturing, product development and marketing of any products resulting from this agreement.

In March 2013, the Company and Novartis amended the right-to-test agreement so that Novartis can take a license to develop and commercialize products directed at two pre-defined and related undisclosed targets, one target licensed on an exclusive basis and the other target initially licensed on a non-exclusive basis. The target licensed on a non-exclusive basis may be converted to an exclusive target by notice and payment to the Company of an agreed-upon fee of at least \$5 million, depending on specific circumstances. The Company received a \$3.5 million fee in connection with the execution of the amendment to the agreement. The Company may be required to credit this fee against future milestone payments if Novartis discontinues the development of a specified product under certain circumstances.

In connection with the amendment, in March 2013, Novartis took the license referenced above under the right-to-test agreement, as amended, enabling it to develop and commercialize products directed at the two targets. The Company received a

Table of Contents

\$1 million upfront fee with the execution of this license. Additionally, the execution of this license provides the Company the opportunity to receive milestone payments totaling \$199.5 million (development milestones \$22.5 million; regulatory milestones \$77 million; and sales milestones \$100 million) or \$238 million (development milestones \$22.5 million; regulatory milestones \$115.5 million; and sales milestones \$100 million), depending on the composition of any resulting products.

In October 2013 and November 2013, Novartis took its second and third exclusive licenses to single targets, each triggering a \$1 million payment to the Company and the opportunity to receive milestone payments totaling \$199.5 million for each license taken, as outlined above, plus royalties on the commercial sales of any resulting products. The next payment the Company could receive would either be a \$5 million development milestone for commencement of a Phase I clinical trial under any of these three licenses, or a \$1 million exercise fee for the execution of a fourth license. At the time of execution of these agreements, 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. Additionally, the Company is entitled to receive royalties on product sales, if any. Novartis also has the right to convert the noted non-exclusive license to an exclusive license, in which case the Company would be entitled to receive, depending on the composition of resultant products, an upward adjustment on milestone payments.

In accordance with ACS 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 and subsequently when amended. The significant deliverables were determined to be the right-to-test, or research, license, the development and commercialization licenses, rights to future technological improvements, 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 Novartis to obtain development and commercialization licenses, (ii) the size of the exercise fee of \$1 million for each development and commercialization license obtained is not significant relative to the \$45 million upfront payment that was due at the inception of the right-to-test agreement, (iii) the limited economic benefit that Novartis 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 Novartis would derive if they did not obtain any development and commercialization licenses. The Company has also determined that this unit of accounting does have stand-alone value from the rights to future technological improvements and the research services. The rights to future technological improvements 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 Novartis would be able to use those items for their intended purpose without the undelivered elements. The research services have stand-alone value as similar services are sold separately by other vendors.

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 the Company's understanding of pricing terms offered by its competitors for single-target development and commercialization licenses that utilize ADC 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 right 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 such technological improvements made will be used by Novartis. 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

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

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 research services was based on third-party evidence given the nature of the research services to be performed for Novartis and market rates for similar services.

Upon payment of the extension fee in October 2013, the total arrangement consideration of \$60.2 million (which comprises the \$45 million upfront payment, the amendment fee of \$3.5 million, the \$5 million extension fee, the exercise fee for each license,

Table of Contents

and the expected fees for the research services to be provided under the remainder of the arrangement) was reallocated to the deliverables based on the relative selling price method as follows: \$55 million to the delivered and undelivered development and commercialization licenses; \$4.5 million to the rights to future technological improvements; and \$710,000 to the research services. The Company recorded \$17.2 million of the \$55 million of the arrangement consideration outlined above for the two development and commercialization licenses taken by Novartis in October 2013 and November 2013, which is included in license and milestone fee revenue for the three and six months ended December 31, 2013. The Company also recorded a cumulative catch-up of \$1 million for the license delivered in March 2013 and the delivered portion of the license covering future technological improvements, which is included in license and milestone fee revenue for the three and six months ended December 31, 2013.

Since execution of the first development and commercialization license taken in March 2013, the amount of the total arrangement consideration allocated to future technological improvements is being recognized as revenue ratably over the period the Company is obligated to make available any technological improvements, which is equivalent to the estimated term of the agreement. 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 products pursuant to the license plus the estimated royalty term. The Company reassesses the estimated term at the end of each reporting period. The Company does not control when Novartis will exercise its options for development and commercialization licenses. As a result, the Company cannot predict when it will recognize the related remaining license revenue except that it will be within the term of the research license. The Company will recognize research services revenue as the related services are delivered.

*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,



Table of Contents

(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.

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 six month period ended December 31, 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

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

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.

In December 2013, the Company 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 six-month periods by payment to the Company 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 the Company an exercise fee of \$2.0 million for the first development and commercialization license, and has the right to elect, at its discretion, which of the

Table of Contents

additional development and commercialization licenses, if any, taken under the right-to-test agreement will have no exercise fee and which will have an exercise fee of \$2.0 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. Due to the contingent nature of the extension fees, the lack of overall change in the total consideration for the licenses and the Company's conclusion that there has been no change in the relative selling prices originally used in the allocation of the consideration, there was no accounting impact upon the execution of the amendment.

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 2013 Form 10-K.

**C. Capital Stock**

*2001 Non-Employee Director Stock Plan*

During the three and six months ended December 31, 2013, the Company recorded approximately \$15,000 and \$12,000 in expense reduction, respectively, related to stock units outstanding under the Company's 2001 Non-Employee Director Stock Plan, or the 2001 Plan, compared to \$12,000 and \$25,000 in expense reduction recorded during the three and six months ended December 31, 2012, respectively. 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 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, 41,805 and 33,187 options in the six months ended December 31, 2013, and fiscal years ended 2013 and 2012, respectively, and the related compensation expense for the three and six months ended December 31, 2013 and 2012 is included in the amounts discussed in the Stock-Based Compensation section of footnote A above.

During the three and six months ended December 31, 2013, the Company recorded approximately \$100,000 and \$197,000 in compensation expense, respectively, related to deferred share units issued and outstanding under the Company's Compensation Policy for Non-Employee Directors, compared to \$78,000 and \$155,000 in compensation expense recorded during the three and six months ended December 31, 2012, respectively. Pursuant to the Compensation Policy for Non-Employee Directors, in November 2013, the Company issued a retiring director 43,615 shares of common stock of the Company to settle outstanding deferred share units.

**D. Cash and Cash Equivalents**

As of December 31, 2013 and June 30, 2013, the Company held \$178.1 million and \$195.0 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. The Company uses this space for its corporate headquarters, research and other operations. The initial term of the lease is for twelve years with an option for the

Table of Contents

Company to extend the lease for two additional terms of five years. 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. 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.

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 initial term of the sublease is for three years with a conditional option for the Company to extend the lease through October 2017. 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 March 2013, the Company entered into a lease agreement for the rental of 43,850 square feet in Norwood, MA 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 August 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.

As of December 31, 2013, 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):

2014 (six months remaining)	\$	3,364
2015		7,677
2016		7,543
2017		7,626
2018		7,843
Thereafter		11,895
Total minimum lease payments	\$	45,948
Total minimum rental payments from sublease		(745)
Total minimum lease payments, net	\$	45,203

*Purchase Obligations*

At December 31, 2013, the Company is obligated to a vendor for certain contractual services to be performed in fiscal 2014. Pursuant to the contract, the Company is required to make a \$1.2 million payment to the vendor unless the contract is terminated by the Company for cause.

*Collaborations*

The Company is contractually obligated to make potential future success-based regulatory milestone payments in conjunction with a certain collaborative agreement. 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 December 31, 2013, the maximum amount that may be payable in the future under the Company's current collaborative agreement is \$2.0 million, \$1.4 million of which is reimbursable by a third party under a separate agreement.

Table of Contents

**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. An ADC compound's antibody component enables it to bind 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 compounds using our proprietary ADC technology 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 expertise in antibodies and cancer biology to develop naked, or non-conjugated, antibody anticancer product candidates.

We have used our proprietary ADC technology in conjunction with our in-house antibody expertise to develop our own anticancer product candidates. We have also entered into collaborative agreements that enable companies to use our ADC technology to develop and commercialize product candidates to specified targets. Under the terms of our collaborative agreements, we are generally entitled to upfront fees, milestone payments and royalties on any commercial product sales. In addition, under certain agreements we are 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 at negotiated prices which are generally consistent with what other third parties would charge. Currently, our collaborative partners are Amgen, Bayer HealthCare, Biotest, Lilly, Novartis, Roche and Sanofi. We expect that substantially all of our revenue for the foreseeable future will result from payments under our collaborative arrangements. Details for some of our collaborative agreements with recent activity follow. Details for our other significant agreements can be found in our 2013 Annual Report on Form 10-K

*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 December 31, 2013, 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 and six months ended December 31, 2013 is the \$5 million milestone payment for marketing approval of Kadcyla in the EU and included in license and milestone fees for the six months ended December 31, 2013 is the \$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, \$2.3 million of royalties on net sales of Kadcyla for the three-month period ended September 30, 2013 were recorded and

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

included in royalty revenue for the three months ended December 31, 2013 and \$4.4 million of royalties on net sales of Kadcyła for the six-month period ended September 30, 2013 is included in royalty revenue for the six months ended December 31, 2013. No such royalties were recorded in the prior year periods.

*Amgen* Under a now-expired right-to-test agreement entered into with Amgen in December 2000, in September 2009, November 2009 and December 2012, Amgen took three exclusive development and commercialization licenses, for which we received an exercise fee of \$1 million for each license taken. In May 2013, Amgen took one non-exclusive development and commercialization license, for which we received an exercise fee of \$500,000. In October 2013, the non-exclusive license was amended and converted to an exclusive license, for which Amgen paid an additional \$500,000 fee to us. For each of these development and commercialization license taken, we are entitled to receive up to a total of \$34 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones per exclusive development and commercialization license are categorized as follows: development milestones \$9 million; regulatory milestones \$20 million; and sales milestones \$5 million. Amgen no longer has the right to take additional options for development and commercialization licenses under the agreement.



Table of Contents

Since a deliverable to the original right-to-test agreement was determined to be materially modified at the time the non-exclusive license was converted to exclusive in October 2013, we accounted for the multiple-element agreement in accordance with ACS 605-25 (as amended by ASU No. 2009-13). As a result, all of the deferred revenue recorded on the date of the modification and the new consideration received as part of the modification was allocated to all of the remaining deliverables at the time of amendment of the right-to-test agreement based on the estimated selling price of each element. The remaining amount represents consideration for previously delivered elements and was recognized upon the execution of the modification.

The outstanding licenses, including the exclusive license delivered upon the signing of the amendment, contain the rights to future technological improvements as well as options to purchase materials and research and development services. We concluded that additional materials and research and development services would be paid at a contractual price equal to the estimated selling price based estimated prices that would be charged by third parties for similar services. The estimated selling price of the right 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 such technological improvements made will be used by Amgen. The \$430,000 determined to be the estimated selling price of the future technological improvements is being recognized as revenue ratably over the period we are obligated to make available any technological improvements, which is equivalent to the estimated term of the agreement, or 25 years. After accounting for the undelivered elements at the estimated selling price, we had \$2.2 million of remaining allocable consideration which was determined to represent consideration for the previously delivered elements, including the exclusive license that was delivered upon the execution of the modification. This amount was recorded as revenue and is included in license and milestone fees for the three and six months ended December 31, 2013.

*Sanofi* 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 our 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. We have deferred the exercise fee and are recognizing the \$2 million as revenue ratably over our estimated period of substantial involvement.

*Novartis* In October 2010, we entered into a three-year right-to-test agreement with Novartis. The agreement provides Novartis with the right to (a) test our ADC technology with individual antibodies selected by Novartis under a right-to-test, or research, license, (b) take exclusive options, with certain restrictions, to individual targets selected by Novartis for specified option periods and (c) upon exercise of those options, take exclusive licenses to use our 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 initial three-year term of the right-to-test agreement was extended by Novartis in October 2013 for an additional one-year period by payment of a \$5 million fee to us. In addition to the one-year extension taken in October 2013, the terms of the right-to-test agreement allow Novartis to extend the research term for one additional one-year period by payment of additional consideration. The terms of the right-to-test agreement require Novartis to exercise its options for the development and commercialization licenses by the end of the term of the research license. We received a \$45 million upfront payment in connection with the execution of the right-to-test agreement, and for each development and commercialization license for a specific target, we are entitled to receive an exercise fee of \$1 million and up to a total of \$199.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$22.5 million; regulatory milestones \$77 million; and sales milestones \$100 million.

Effective March 29, 2013, we and Novartis amended the right-to-test agreement so that Novartis can take a license to develop and commercialize products directed at two pre-defined and related undisclosed targets, one target licensed on an exclusive basis and the other target initially licensed on a non-exclusive basis. The target licensed on a non-exclusive basis may be converted to an exclusive target by notice and payment to us of an agreed-upon fee of at least \$5 million, depending on specific circumstances. We received a \$3.5 million fee in connection

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

with the execution of the amendment to the agreement. We may be required to credit this fee against future milestone payments if Novartis discontinues the development of a specified product under certain circumstances.

In connection with the amendment, on March 29, 2013, Novartis took the license referenced above under the right-to-test agreement, as amended, enabling it to develop and commercialize products directed at the two targets. We received a \$1 million upfront fee with the execution of this license. Additionally, the execution of this license provides us the opportunity to receive milestone payments totaling \$199.5 million (development milestones \$22.5 million; regulatory milestones \$77 million; and sales milestones \$100 million) or \$238 million (development milestones \$22.5 million; regulatory milestones \$115.5 million; and sales milestones \$100 million), depending on the composition of any resulting products. Additionally, under the license agreements, we are entitled to receive royalties on product sales, if any. Novartis also has the right to convert the noted non-exclusive license to an

Table of Contents

exclusive license, in which case we would be entitled to receive a conversion fee and, depending on the composition of resultant products, an upward adjustment on milestone payments. In October 2013 and November 2013, Novartis took its second and third exclusive license to a single target, each triggering a \$1 million payment to us and the opportunity to receive milestone payments totaling \$199.5 million for each license taken, as outlined above. In accordance with our revenue recognition policy, upon execution of the development and commercialization licenses taken by Novartis in October 2013 and November 2013 and payment of the one-year extension fee, we recorded \$17.2 million of revenue, which is included in license and milestone fee revenue for the three and six months ended December 31, 2013. We also recorded a cumulative catch-up of \$1 million for the license delivered in March 2013 and the delivered portion of the license covering future technological improvements, which is included in license and milestone fee revenue for the three and six months ended December 31, 2013.

*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 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 six-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 six months ended December 31, 2013.

To date, we have not generated revenues from our proprietary commercial product sales and we expect to incur significant operating losses for the foreseeable future. As of December 31, 2013, we had approximately \$178.1 million in cash and cash equivalents compared to \$195.0 million in cash and cash equivalents as of June 30, 2013.

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 operating results may fluctuate dramatically based upon the timing of receipt of the proceeds. We believe that our established collaboration agreements, while subject to specified milestone achievements, will provide funding to assist us in meeting obligations under our collaborative agreements while also 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

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

required to pursue additional strategic partners, secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects. However, we cannot provide assurance that any such opportunities presented by additional strategic partners or alternative financing arrangements will be entirely available to us, if at all.

### *Critical Accounting Policies*

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our

Table of Contents

estimates, including those related to our collaborative agreements, 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, 2013.

**RESULTS OF OPERATIONS***Comparison of Three Months ended December 31, 2013 and 2012**Revenues*

Our total revenues for the three months ended December 31, 2013 and 2012 were \$30.1 million and \$2.6 million, respectively. The \$27.5 million increase in revenues in the three months ended December 31, 2013 from the same period in the prior year is attributable to an increase in license and milestone fees and royalty revenue, partially offset by a decrease in research and development support revenue and clinical materials revenue, all of which are discussed below.

Revenues from license and milestone fees for the three months ended December 31, 2013 increased \$25.2 million to \$25.7 million from \$429,000 in the same period ended December 31, 2012. Included in license and milestone fees for the three months ended December 31, 2013 is a \$5 million regulatory milestone achieved under our collaboration agreement with Roche, \$18.2 million of license revenue earned upon the execution of two development and commercialization licenses and a one-year extension of the original term of the multi-target agreement by Novartis and \$2.2 million of revenue from Amgen related to a modification of an existing arrangement. 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 December 31, 2013 and 2012 is included in the following table (in thousands):

License and Milestone Fees Collaborative Partner:	Three Months Ended December 31,	
	2013	2012
Amgen	\$ 2,227	\$ 256
Biotest	7	6
Lilly	6	
Novartis	18,221	
Sanofi	217	167
Roche	5,000	
Total	\$ 25,678	\$ 429

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

Deferred revenue of \$49.0 million as of December 31, 2013 primarily represents payments received from our collaborators pursuant to our license agreements, which we have yet to earn pursuant to our revenue recognition policy.

In February 2013, the U.S. FDA granted marketing approval to Kadcyra, 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 Kadcyra from Roche one quarter in arrears. In accordance with our revenue recognition policy, \$2.3 million of royalties on net sales of Kadcyra for the three-month period ended September 30, 2013 were recorded and included in royalty revenue for the three months ended December 31, 2013. No royalty revenue was recorded in the three-month period ended December 31, 2012. We expect royalty revenue to increase in future periods as the underlying net sales of Kadcyra increase.

Research and development support revenue was \$1.9 million for the three months ended December 31, 2013 compared with \$2.0 million for the three months ended December 31, 2012. 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

Table of Contents

recognized from research and development support from each of our collaborative partners in the three-month periods ended December 31, 2013 and 2012 is included in the following table (in thousands):

Research and Development Support Collaborative Partner:	Three Months Ended December 31,	
	2013	2012
Amgen	\$ 204	\$ 128
Biotest	225	338
Lilly	612	200
Novartis	870	1,370
Other	11	
Total	\$ 1,922	\$ 2,036

Clinical materials revenue decreased \$22,000 in the three months ended December 31, 2013 to \$125,000 from \$147,000 in the three months ended December 31, 2012. 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 December 31, 2013 decreased \$794,000 to \$20.9 million from \$21.7 million for the three months ended December 31, 2012. The decrease was primarily due to decreased costs for third-party production of antibody and costs to fill conjugated material for use in clinical materials due to timing, decreased clinical trial costs driven by the termination of the IMG901 Phase II trial in the current period and an increase in costs capitalized into inventory due to a greater number of manufactured batches of conjugated materials on behalf of our collaborators. Partially offsetting these decreases, 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 256 as of December 31, 2013 compared to 225 at December 31, 2012. The higher stock compensation is driven by higher stock prices and increases in the number the number of options granted due to increases in personnel. 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

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

preclinical testing and move into our internal clinical development program. The clinical trial and regulatory approval processes for our product candidates that have advanced or that we intend to advance to clinical testing are lengthy, expensive and uncertain in both timing and outcome. As a result, the pace and timing of the clinical development of our product candidates is highly uncertain and may not ever result in approved products. Completion dates and development costs will vary significantly for each product candidate and are difficult to predict. A variety of factors, many of which are outside our control, could cause or contribute to the prevention or delay of the successful completion of our clinical trials, or delay or prevent our obtaining necessary regulatory approvals. The costs to take a product through clinical trials are dependent upon, among other factors, 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.



Table of Contents

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

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

Research and Development Expense	Three Months Ended December 31,	
	2013	2012
Research	\$ 4,144	\$ 4,280
Preclinical and Clinical Testing	7,320	6,998
Process and Product Development	1,962	1,874
Manufacturing Operations	7,436	8,504
Total Research and Development Expense	\$ 20,862	\$ 21,656

*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, facilities and lab supplies. Research expenses for the three months ended December 31, 2013 decreased \$136,000 compared to the three months ended December 31, 2012. We expect research expenses for fiscal 2014 to be marginally higher than fiscal 2013.

*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 December 31, 2013 increased \$322,000 to \$7.3 million compared to \$7.0 million for the three months ended December 31, 2012. This increase is primarily the result of higher salaries and related expenses, partially offset by a decrease in clinical trial costs due primarily to the termination of the IMGN901 007 Phase II study for small-cell lung cancer. We expect preclinical and clinical testing expenses for fiscal 2014 to be significantly higher than fiscal 2013 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 December 31, 2013, total development expenses increased \$88,000 compared to the three months ended December 31, 2012. We expect process and product development expenses for fiscal 2014 to be marginally higher than fiscal 2013.

*Manufacturing Operations:* Manufacturing operations expense includes costs to manufacture preclinical and clinical materials for our own and our collaborators' product candidates, and quality control and quality assurance activities and costs to support the operation and maintenance of our conjugate manufacturing facility. Such expenses include personnel, raw materials for our and our collaborators' preclinical studies and clinical trials, development costs with contract manufacturing organizations, manufacturing supplies, and facilities expense. For the three months ended December 31, 2013, manufacturing operations expense decreased \$1.1 million to \$7.4 million compared to \$8.5 million in the same period last year. The decrease in the three months ended December 31, 2013 as compared to the three months ended December 31, 2012 is

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

primarily the result of (i) a decrease in antibody development and supply expense driven primarily by supply required for our IMG289 program and pivotal activities for our IMG901 program during the prior period, partially offset by supply required for our IMG853 program and development activities for an earlier-stage program during the current period; (ii) a decrease in cost of clinical materials revenue due primarily to lower amounts of DMx written off as excess; and (iii) an increase in costs capitalized into inventory due to a greater number of manufactured batches of conjugated materials on behalf of our collaborators. Partially offsetting these decreases, salaries and related expenses increased during the current period and contract service expense increased due primarily to increased study activities related to our cytotoxic agents. We expect manufacturing operations expense for fiscal 2014 to be significantly higher than fiscal 2013 due primarily to increased activities to advance our wholly owned product candidates.

### *General and Administrative Expenses*

General and administrative expenses for the three months ended December 31, 2013 decreased \$17,000 to \$5.4 million from the three months ended December 31, 2012. We expect general and administrative expenses for fiscal 2014 to be higher than fiscal 2013 due primarily to increased patent activities, consulting fees and other professional services.

Table of Contents*Other Income, net*

Other income, net for the three months ended December 31, 2013 and 2012 is included in the following table (in thousands):

<b>Other Income, net</b>	<b>Three Months Ended December 31,</b>			
	<b>2013</b>		<b>2012</b>	
Interest Income	\$	10	\$	39
Other Income, net		52		76
Total Other Income, net	\$	62	\$	115

*Comparison of Six Months ended December 31, 2013 and 2012**Revenues*

Our total revenues for the six months ended December 31, 2013 and 2012 were \$47.3 million and \$6.7 million, respectively. The \$40.6 million increase in revenues in the six months ended December 31, 2013 from the same period in the prior year is attributable to an increase in license and milestone fees, royalty revenue and research and development support revenue, partially offset by a decrease in clinical materials revenue, all of which are discussed below.

Revenues from license and milestone fees for the six months ended December 31, 2013 increased \$37.5 million to \$38.9 million from \$1.4 million in the same period ended December 31, 2012. Included in license and milestone fees for the six months ended December 31, 2013 is \$7.8 million of license revenue earned upon the execution of a development and commercialization license by Lilly, two \$5 million regulatory milestones achieved under our collaboration agreement with Roche, \$18.2 million of license revenue earned upon the execution of two development and commercialization licenses and a one-year extension of the original term of the multi-target agreement by Novartis and \$2.2 million of revenue from Amgen related to a modification of an existing arrangement. 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 six-month periods ended December 31, 2013 and 2012 is included in the following table (in thousands):

<b>License and Milestone Fees</b>	<b>Six Months Ended December 31,</b>			
	<b>2013</b>		<b>2012</b>	
Collaborative Partner:				
Amgen	\$	2,343	\$	496
Bayer HealthCare				521
Biotest		13		12
Lilly		7,818		
Novartis		18,262		
Sanofi		409		333
Roche		10,000		
Total	\$	38,845	\$	1,362

In February 2013, the U.S. FDA granted marketing approval to Kadcyra, 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 Kadcyra from Roche one quarter in arrears. In accordance with our revenue recognition policy, \$4.4 million of royalties on net sales of Kadcyra for the six-month period ended September 30, 2013 were recorded and included in royalty revenue for the six months ended December 31, 2013. No royalty revenue was recorded in the six-month period ended December 31, 2012. We expect royalty revenue to increase in future periods as the underlying net sales of Kadcyra increase.

Research and development support revenue was \$3.9 million for the six months ended December 31, 2013 compared with \$3.4 million for the six months ended December 31, 2012. 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 research and development support from each of our collaborative partners in the six-month periods ended December 31, 2013 and 2012 is included in the following table (in thousands):

Table of Contents

Research and Development Support	Six Months Ended December 31,	
	2013	2012
Collaborative Partner:		
Amgen	\$ 270	\$ 212
Biotest	464	453
Lilly	1,140	423
Novartis	2,025	2,318
Other	13	7
Total	\$ 3,912	\$ 3,413

Clinical materials revenue decreased \$1.8 million in the six months ended December 31, 2013 to \$133,000 from \$1.9 million in the six months ended December 31, 2012. 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*

Research and development expense for the six months ended December 31, 2013 decreased \$2.5 million to \$42.9 million from \$45.3 million for the six months ended December 31, 2012. The decrease was primarily due to decreased costs for third-party production of antibody and costs to fill conjugated material for use in clinical materials due to timing, as well as a decrease in cost of clinical materials revenue due to timing of orders of such clinical materials from our partners and lower amounts of DMx written off as excess. Partially offsetting these decreases, salaries and related expenses increased due to additional headcount, increased incentive compensation and increased stock compensation costs.

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

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

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):

Table of Contents

Research and Development Expense	Six Months Ended December 31,	
	2013	2012
Research	\$ 8,702	\$ 8,589
Preclinical and Clinical Testing	15,932	13,849
Process and Product Development	4,000	3,836
Manufacturing Operations	14,257	19,082
Total Research and Development Expense	\$ 42,891	\$ 45,356

*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, facilities and lab supplies. Research expenses for the six months ended December 31, 2013 increased \$113,000 compared to the six months ended December 31, 2012. This increase is primarily the result of an increase in salaries and related expenses. We expect research expenses for fiscal 2014 to be marginally higher than fiscal 2013.

*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 six months ended December 31, 2013 increased \$2.1 million to \$15.9 million compared to \$13.8 million for the six months ended December 31, 2012. This increase is primarily the result of higher salaries and related expenses, partially offset by a decrease in contract service expense driven by less third-party studies conducted during the current period for the IMGN289 program and an earlier-stage program as compared to the prior year period. We expect preclinical and clinical testing expenses for fiscal 2014 to be significantly higher than fiscal 2013 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 six months ended December 31, 2013, total development expenses increased \$164,000 compared to the six months ended December 31, 2012. This increase is primarily the result of an increase in salaries and related expenses. We expect process and product development expenses for fiscal 2014 to be marginally higher than fiscal 2013.

*Manufacturing Operations:* Manufacturing operations expense includes costs to manufacture preclinical and clinical materials for our own and our collaborator's product candidates, and quality control and quality assurance activities and costs to support the operation and maintenance of our conjugate manufacturing facility. Such expenses include personnel, raw materials for our and our collaborators' preclinical studies and clinical trials, development costs with contract manufacturing organizations, manufacturing supplies, and facilities expense. For the six months ended December 31, 2013, manufacturing operations expense decreased \$4.8 million to \$14.3 million compared to \$19.1 million in the same period last year. The decrease in the six months ended December 31, 2013 as compared to the six months ended December 31, 2012 is primarily the result of (i) a decrease in antibody development and supply expense driven primarily by supply required for our IMGN289 and IMGN901 programs and pivotal activities for our IMGN901 program during the prior period, partially offset by supply required for our IMGN853 program and development activities for an earlier-stage program during the current period; (ii) a decrease in cost of clinical materials revenue due to timing of orders of such clinical materials from our partners and lower amounts of DMx written off as excess; (iii) a decrease in fill/finish costs due primarily to costs to transfer our internal programs to a new supplier during the prior year period; and (iv) an increase in costs capitalized into inventory due to a greater number of manufactured batches of conjugated materials on behalf of our collaborators. Partially offsetting these decreases, salaries and related expenses increased during the current period and contract service expense increased due primarily to increased study activities related to our cytotoxic agents. We expect manufacturing operations expense for fiscal 2014 to be significantly higher than fiscal 2013 due primarily to increased activities to advance our wholly owned product candidates.

*General and Administrative Expenses*

General and administrative expenses for the six months ended December 31, 2013 increased \$870,000 to \$12.0 million compared to \$11.1 million for the six months ended December 31, 2012. This increase is primarily due to an increase in salaries and related expenses, as well as an increase in professional service fees, particularly consulting fees and patent expenses. We expect general and administrative expenses for fiscal 2014 to be higher than fiscal 2013 due primarily to increased patent activities, consulting fees and other professional services.

*Other Income, net*

Other income, net for the six months ended December 31, 2013 and 2012 is included in the following table (in thousands):

<b>Other Income, net</b>	<b>Six Months Ended December 31,</b>	
	<b>2013</b>	<b>2012</b>
Interest Income	\$ 21	\$ 85
Other Income, net	151	86
<b>Total Other Income, net</b>	<b>\$ 172</b>	<b>\$ 171</b>



Table of Contents**LIQUIDITY AND CAPITAL RESOURCES**

	<b>December 31, 2013</b>	<b>As of June 30, 2013</b>
	<b>(In thousands)</b>	
Cash and cash equivalents	\$ 178,088	\$ 194,960
Working capital	171,825	181,511
Shareholders' equity	130,036	121,847

	<b>Six Months Ended December 31, 2013</b>		<b>2012</b>
	<b>(In thousands)</b>		
Cash used for operating activities	\$ (21,629)	\$	(42,709)
Cash used for investing activities	(2,298)		(2,050)
Cash provided by financing activities	7,055		94,842

*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 and research funding. In fiscal year 2013, we also began to receive royalties from one collaborator. As of December 31, 2013, we had approximately \$178.1 million in cash and cash equivalents. Net cash used for operations was \$21.6 million and \$42.7 million for the six months ended December 31, 2013 and 2012, respectively. The principal use of cash for operating activities for both periods presented was to fund our net loss, adjusted for non-cash items.

Net cash used for investing activities was \$2.3 million and \$2.1 million for the six months ended December 31, 2013 and 2012, respectively, and primarily represents cash outflows for capital expenditures. Capital expenditures, primarily for the purchase of new equipment and leasehold improvements, were \$2.3 million and \$2.0 million for the six-month periods ended December 31, 2013 and 2012, respectively.

Net cash provided by financing activities was \$7.1 million and \$94.8 million for the six months ended December 31, 2013 and 2012, respectively, which represents proceeds from the exercise of approximately 861,000 and 128,000 stock options, respectively. Also, pursuant to a public offering in the prior year period, we issued and sold 6,250,000 shares of our common stock resulting in net proceeds of \$94.0 million.

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 at least through fiscal year 2015. 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 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*

The Company is obligated to a vendor for certain contractual services to be performed in fiscal 2014. Pursuant to the contract, the Company is required to make a \$1.2 million payment to the vendor unless the contract is terminated by the Company for cause. There have been no other 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, 2013.

*Recent Accounting Pronouncements*

In July 2013, the FASB issued guidance to address the diversity in practice related to the financial statement presentation of unrecognized tax benefits as either a reduction of a deferred tax asset or a liability when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. This guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

Table of Contents

*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, 2013. 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, 2013. 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*

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

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.

(b) *Changes in Internal Controls*

There have not been any changes in the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2013 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Table of Contents**PART II. OTHER INFORMATION****ITEM 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, 2013. There have been no material changes from the factors disclosed in our 2013 Annual Report on Form 10-K, although we may disclose changes to such factors or disclose additional factors from time to time in our future filings with the Securities and Exchange Commission.

**ITEM 6. Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
10.1	First Amendment to Lease Agreement dated December 9, 2013 by and between Intercontinental Fund II 830 Winter Street LLC, landlord, and the Registrant
10.2*	First Amendment to Agreements dated as of December 9, 2013 by and between the Registrant and Eli Lilly and Company
10.3	Compensation Policy for Non-Employee Directors, as amended through November 12, 2013
10.4	Employment offer letter between the Registrant and David B. Johnston
10.5	Employment agreement dated as of December 30, 2013 between the Registrant and David B. Johnston
10.6	Change in Control Severance Agreement dated as of December 30, 2013 between the Registrant and David B. Johnston
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

---

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

*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: February 5, 2014

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

Date: February 5, 2014

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