

IMMUNOGEN INC
Form 10-Q
May 04, 2016
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 March 31, 2016

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: 87,076,978 shares outstanding as of April 28, 2016.

Table of Contents

IMMUNOGEN, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2016

TABLE OF CONTENTS

Item		Page Number
	Part I	
<u>1.</u>	<u>Financial Statements (Unaudited):</u>	
<u>1a.</u>	<u>Consolidated Balance Sheets as of March 31, 2016 and June 30, 2015</u>	2
<u>1b.</u>	<u>Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended March 31, 2016 and 2015</u>	3
<u>1c.</u>	<u>Consolidated Statements of Cash Flows for the nine months ended March 31, 2016 and 2015</u>	4
<u>1d.</u>	<u>Notes to Consolidated Financial Statements</u>	5
<u>2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
<u>3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	32
<u>4.</u>	<u>Controls and Procedures</u>	32
	Part II	
<u>1A.</u>	<u>Risk Factors</u>	32
<u>6.</u>	<u>Exhibits</u>	33
	<u>Signatures</u>	34

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

	March 31, 2016	June 30, 2015
ASSETS		
Cash and cash equivalents	\$ 182,913	\$ 278,109
Accounts receivable	104	5,088
Unbilled revenue	1,027	714
Inventory	908	2,935
Current portion of deferred financing costs	1,018	1,159
Prepaid and other current assets	7,334	4,175
Total current assets	193,304	292,180
Property and equipment, net of accumulated depreciation	22,404	16,254
Deferred financing costs, net of current portion	3,714	4,415
Other assets	2,925	974
Total assets	\$ 222,347	\$ 313,823
LIABILITIES AND SHAREHOLDERS EQUITY		
Accounts payable	\$ 10,100	\$ 8,138
Accrued compensation	6,589	8,346
Other accrued liabilities	9,150	10,441
Current portion of deferred lease incentive	651	646
Current portion of liability related to the sale of future royalties	13,001	7,906
Current portion of deferred revenue	339	333
Total current liabilities	39,830	35,810
Deferred lease incentive, net of current portion	5,836	6,301
Deferred revenue, net of current portion	32,015	40,855
Liability related to the sale of future royalties, net of current portion	181,636	191,756
Other long-term liabilities	4,173	3,997
Total liabilities	263,490	278,719
Commitments and contingencies (Note F)		
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 87,077 and 86,579 shares as of March 31, 2016 and June 30, 2015, respectively	871	866
Additional paid-in capital	765,751	743,108
Accumulated deficit	(807,765)	(708,870)
Total shareholders' equity	(41,143)	35,104
Total liabilities and shareholders' equity	\$ 222,347	\$ 313,823

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

Table of Contents

IMMUNOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

In thousands, except per share amounts

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2016	2015	2016	2015
Revenues:				
License and milestone fees	\$ 10,077	\$ 5,078	\$ 26,839	\$ 52,729
Royalty revenue		5,099	195	13,890
Non-cash royalty revenue related to the sale of future royalties	7,380		19,355	
Research and development support	1,059	532	2,679	2,140
Clinical materials revenue	1,198	718	3,526	4,171
Total revenues	19,714	11,427	52,594	72,930
Operating Expenses:				
Research and development	36,094	25,666	109,425	81,331
General and administrative	11,235	7,000	27,618	20,967
Total operating expenses	47,329	32,666	137,043	102,298
Loss from operations	(27,615)	(21,239)	(84,449)	(29,368)
Investment income, net	108	14	219	36
Non-cash interest expense on liability related to the sale of future royalties	(4,972)		(15,174)	
Other income (expense), net	551	(393)	509	(933)
Net loss	\$ (31,928)	\$ (21,618)	\$ (98,895)	\$ (30,265)
Basic and diluted net loss per common share	\$ (0.37)	\$ (0.25)	\$ (1.14)	\$ (0.35)
Basic and diluted weighted average common shares outstanding				
	87,035	86,080	86,948	85,962
Total comprehensive loss	\$ (31,928)	\$ (21,618)	\$ (98,895)	\$ (30,265)

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

	Nine Months ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (98,895)	\$ (30,265)
Adjustments to reconcile net loss to net cash used for operating activities:		
Non-cash royalty revenue related to sale of future royalties	(19,355)	
Non-cash interest expense on liability related to sale of future royalties	15,174	
Depreciation and amortization	3,822	4,231
Gain on sale/disposal of fixed assets	(29)	(7)
Stock and deferred share unit compensation	17,668	12,804
Deferred rent	97	161
Changes in operating assets and liabilities:		
Accounts receivable	4,984	1,142
Unbilled revenue	(313)	793
Inventory	2,027	248
Prepaid and other current assets	(3,159)	(467)
Other assets	(1,951)	170
Accounts payable	796	1,503
Accrued compensation	(1,757)	306
Other accrued liabilities	(1,844)	639
Deferred revenue	(8,834)	(19,446)
Proceeds from landlord for tenant improvements		1,350
Net cash used for operating activities	(91,569)	(26,838)
Cash flows from investing activities:		
Purchases of property and equipment	(8,606)	(4,506)
Payments for transaction costs related to sale of future royalties		(522)
Net cash used for investing activities	(8,606)	(5,028)
Cash flows from financing activities:		
Proceeds from stock options exercised	4,979	1,432
Net cash provided by financing activities	4,979	1,432
Net change in cash and cash equivalents	(95,196)	(30,434)
Cash and cash equivalents, beginning balance	278,109	142,261
Cash and cash equivalents, ending balance	\$ 182,913	\$ 111,827

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

Table of Contents

IMMUNOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2016

A. Nature of Business and Plan of Operations

ImmunoGen, Inc. (the Company) was incorporated in Massachusetts in 1981 and is focused on the development of antibody-based anticancer therapeutics. The Company has incurred operating losses and negative cash flows from operations since inception, incurred a net loss of \$98.9 million during the nine months ended March 31, 2016, and has an accumulated deficit of \$807.8 million as of March 31, 2016. The Company has primarily funded these losses through payments received from its collaborations and equity financings. To date, the Company has no product revenue and management expects operating losses to continue for the foreseeable future.

At March 31, 2016, the Company had \$182.9 million of cash and cash equivalents on hand. The Company anticipates that its current capital resources and expected future collaborator payments under existing collaborations will enable it to meet its operational expenses and capital expenditures through fiscal year 2017. The Company may raise additional funds through equity or debt financings or generate revenues from collaborative partners through a combination of upfront license payments, milestone payments, royalty payments, research funding, and clinical material reimbursement. There can be no assurance that the Company will be able to obtain additional debt or equity financing or generate revenues from collaborative partners on terms acceptable to the Company or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition and require the Company to defer or limit some or all of its research, development and/or clinical projects.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, the development by its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, manufacturing and marketing limitations, collaboration arrangements, third-party reimbursements and compliance with governmental regulations.

B. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements at March 31, 2016 and June 30, 2015 and for the three and nine months ended March 31, 2016 and 2015 include the accounts of ImmunoGen, Inc., or the Company, and its wholly owned subsidiaries, ImmunoGen Securities Corp., ImmunoGen Europe Limited and Hurricane, LLC. 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. The June 30, 2015 condensed consolidated balance sheet data presented for comparative purposes was derived from our audited financial statements but 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

Edgar Filing: IMMUNOGEN INC - Form 10-Q

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, 2015.

Subsequent Events

The Company has evaluated all events or transactions that occurred after March 31, 2016 up through the date the Company issued these financial statements. The Company did not have any material recognizable or unrecognizable subsequent events during this period.

Revenue Recognition

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

Table of Contents

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 if certain criteria are met, including whether the delivered element has stand-alone value to the collaborator. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units.

At March 31, 2016, the Company had the following two types of agreements with the parties identified below:

- Development and commercialization licenses, which provide the party with the right to use the Company's ADC technology and/or certain other intellectual property to develop compounds to a specified antigen target:

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

Bayer (one exclusive single-target license)

Biotest (one exclusive single-target license)

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

Table of Contents

CytomX (one exclusive single-target license)

Lilly (three exclusive single-target licenses)

Novartis (five 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)

Takeda, through its wholly owned subsidiary, Millennium Pharmaceuticals, Inc. (one exclusive single-target license)

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

CytomX

Takeda

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, regardless of patent protection. Royalty rates may vary over the royalty term depending on the Company's intellectual property rights and/or the presence of comparable competing products. The Company may provide technical assistance and share any technology improvements with its collaborators during the term of the collaboration agreements. The Company does not directly control when or whether any collaborator will request research or manufacturing services, achieve milestones or become liable for royalty payments. As a result, the Company cannot predict when or if it will recognize revenues in connection with any of the foregoing.

In determining the units of accounting, management evaluates whether the license has stand-alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of ADC technology research expertise in the general marketplace. If the Company concludes that the license has stand-alone value and therefore will be accounted for as a separate unit of accounting, the Company then determines the estimated selling prices of the license and all other units of accounting based on market conditions, similar arrangements entered into by third parties, and entity-specific factors such as the terms of the Company's previous collaborative agreements, recent preclinical and clinical testing results of therapeutic products that use the Company's ADC technology, the Company's pricing practices and pricing objectives, the likelihood that technological improvements will be made, and, if made, will be used by the Company's collaborators and the nature of the research services to be performed on behalf of its collaborators and market rates for similar services.

Upfront payments on development and commercialization licenses 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.

Table of Contents

The Company recognizes revenue related to research services that represent separate units of accounting as they are performed, as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is probable. The Company recognizes revenue related to the rights to future technological improvements over the estimated term of the applicable license.

The Company may also provide cytotoxic agents to its collaborators or produce preclinical and clinical materials at negotiated prices which are generally consistent with what other third parties would charge. The Company recognizes revenue on cytotoxic agents and on preclinical and clinical materials when the materials have passed all quality testing required for collaborator acceptance and title and risk of loss have transferred to the collaborator. Arrangement consideration allocated to the manufacture of preclinical and clinical materials in a multiple-deliverable arrangement is below the Company's full cost, and the Company's full cost is not expected to ever be below its contract selling prices for its existing collaborations. During the nine months ended March 31, 2016 and 2015, 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 \$7.6 million and \$8.7 million, respectively. The majority of the Company's costs to produce these preclinical and clinical materials are fixed and then allocated to each batch based on the number of batches produced during the period. Therefore, the Company's costs to produce these materials are significantly impacted by the number of batches produced during the period. The volume of preclinical and clinical materials the Company produces is directly related to the number of clinical trials the Company and its collaborators are preparing for or currently have underway, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period such trials last. Accordingly, the volume of preclinical and clinical materials produced, and therefore the Company's per-batch costs to manufacture these preclinical and clinical materials, may vary significantly from period to period.

The Company may also produce research material for potential collaborators under material transfer agreements. Additionally, the Company performs research activities, including developing antibody specific conjugation processes, on behalf of its collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. The Company records amounts received for research materials produced or services performed as a component of research and development support revenue. The Company also develops conjugation processes for materials for later-stage testing and commercialization for certain collaborators. The Company is compensated at negotiated rates and may receive milestone payments for developing these processes which are recorded as a component of research and development support revenue.

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

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

Edgar Filing: IMMUNOGEN INC - Form 10-Q

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 the Company does not contribute effort to the achievement of such milestones are generally achieved after the period of substantial involvement and are recognized as revenue upon achievement of the milestone, as there are no undelivered elements remaining and no continuing performance obligations, assuming all other revenue recognition criteria are met.

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

Table of Contents

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. None of the Company's right-to-test agreements entered into subsequent to the adoption of Accounting Standards Update (ASU) No. 2009-13, *Revenue Arrangements with Multiple Deliverables* on July 1, 2010 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. 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.

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.

Financial Instruments and Concentration of Credit Risk

Cash and cash equivalents are primarily maintained with three financial institutions in the U.S. Deposits with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal 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. Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and marketable securities. The Company held no marketable securities as of March 31, 2016 and June 30, 2015. The Company's investment policy, approved by the Board of Directors, limits the amount it may invest in any one type of investment, thereby reducing credit risk concentrations.

Cash and Cash Equivalents

All highly liquid financial instruments with maturities of three months or less when purchased are considered cash equivalents. As of March 31, 2016 and June 30, 2015, the Company held \$182.9 million and \$278.1 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.

Non-cash Investing Activities

The Company had \$1.3 million of accrued capital expenditures as of March 31, 2016 which have been treated as a non-cash investing activity and, accordingly, are not reflected in the consolidated statement of cash flows. Accrued capital expenditures as of March 31, 2015 were not material and are included in the consolidated statement of cash flows.

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:

Table of Contents

- 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 March 31, 2016, 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 March 31, 2016 (in thousands):

		Fair Value Measurements at March 31, 2016 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	Total			
Cash equivalents	\$ 157,585	\$ 157,585	\$	\$

As of June 30, 2015, 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, 2015 (in thousands):

		Fair Value Measurements at June 30, 2015 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	Total			
Cash equivalents	\$ 269,304	\$ 269,304	\$	\$

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

Unbilled Revenue

The majority of the Company's unbilled revenue at March 31, 2016 and June 30, 2015 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 March 31, 2016 and June 30, 2015 is summarized below (in thousands):

	March 31, 2016	June 30, 2015
Raw materials	\$ 318	\$ 279
Work in process	590	2,656
Total	\$ 908	\$ 2,935

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 \$966,000 of expense related to excess inventory during the nine-months ended March 31, 2016 compared to \$42,000 and \$434,000 of expense related to excess inventory recorded during the three and nine month periods ended March 31, 2015, respectively. There were no expenses recorded for excess inventory during the three-month period ended March 31, 2016.

Table of Contents

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

Computation of Net Loss per Common Share

Basic and diluted net loss per share is calculated based upon the weighted average number of common shares outstanding during the period. During periods of income, participating securities are allocated a proportional share of income determined by dividing total weighted average participating securities by the sum of the total weighted average common shares and participating securities (the two-class method). Shares of the Company's restricted stock participate 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. Diluted (loss) income per share is computed after giving consideration to the dilutive effect of stock options and restricted stock that are outstanding during the period, except where such non-participating securities would be anti-dilutive. Securities which were considered anti-dilutive and which could potentially dilute basic earnings per share in the future were as follows (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2016	2015	2016	2015
Options outstanding to purchase common stock and unvested restricted stock	11,679	10,158	11,679	10,158
Common stock equivalents under treasury stock method	361	451	929	738

Stock-Based Compensation

As of March 31, 2016, 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 11, 2014, an amendment to the 2006 Plan was approved and an additional 5,500,000 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 17,500,000 shares of the Company's common stock, as well as 1,676,599 shares of common stock which represent awards granted under the previous stock option plan, the ImmunoGen, Inc. Restated Stock Option Plan, or the Former Plan, that were forfeited, expired or were cancelled without delivery of shares of common stock or which resulted in the forfeiture of shares of common stock back to the Company between November 11, 2006 and June 30, 2014. Option awards are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Options vest at various periods of up to four years and may be exercised within ten years of the date of grant.

The stock-based awards are accounted for under ASC Topic 718, Compensation - Stock Compensation. Pursuant to Topic 718, the estimated grant date fair value of awards is charged to the statement of operations and comprehensive loss over the requisite service period, which is the vesting period. Such amounts have been reduced by an estimate of forfeitures of all unvested awards. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model with the assumptions noted in the following table. As the Company has not paid dividends since inception, nor does it expect to pay any dividends for the foreseeable future, the expected dividend yield assumption is zero. Expected volatility is based exclusively on historical volatility data of the Company's stock. The expected term of stock options granted is based

Edgar Filing: IMMUNOGEN INC - Form 10-Q

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 March 31,		Nine Months Ended March 31,	
	2016	2015	2016	2015
Dividend	None	None	None	None
Volatility	63.90%	60.76%	66.66%	60.46%
Risk-free interest rate	1.61%	1.67%	1.85%	1.86%
Expected life (years)	6.3	6.3	6.3	6.3

Table of Contents

Using the Black-Scholes option-pricing model, the weighted average grant date fair values of options granted during the three months ended March 31, 2016 and 2015 were \$5.55 and \$3.83 per share, respectively, and \$9.70 and \$6.06 per share for options granted during the nine months ended March 31, 2016 and 2015, respectively.

Stock compensation expense related to stock options and restricted stock awards granted under the 2006 Plan was \$7.2 million and \$17.4 million during the three and nine months ended March 31, 2016, respectively, compared to stock compensation expense of \$3.6 million and \$12.5 million for the three and nine months ended March 31, 2015, respectively. During the three and nine months ended March 31, 2016, the Company recorded approximately \$2.8 million of compensation expense related to the modification of the terms of certain options previously granted to the CEO of the Company in connection with his planned retirement from the Company.

As of March 31, 2016, the estimated fair value of unvested employee awards was \$29.4 million, net of estimated forfeitures. The weighted-average remaining vesting period for these awards is approximately two years.

During the nine months ended March 31, 2016, holders of options issued under the Company's equity plans exercised their rights to acquire an aggregate of approximately 498,000 shares of common stock at prices ranging from \$3.19 to \$17.00 per share. The total proceeds to the Company from these option exercises were approximately \$5.0 million.

Segment Information

During the nine months ended March 31, 2016, the Company continued to operate in one operating segment which is the business of discovery of monoclonal antibody-based anticancer therapeutics.

The percentages of revenues recognized from significant customers of the Company in the three and nine months ended March 31, 2016 and 2015 are included in the following table:

Collaborative Partner:	Three Months Ended March 31,		Nine Months Ended March 31,	
	2016	2015	2016	2015
Bayer	51%	%	19%	%
Lilly	7%	1%	13%	24%
Novartis	%	44%	1%	44%
Roche	37%	45%	37%	19%
Takeda	1%	%	18%	%

There were no other customers of the Company with significant revenues in the three and nine months ended March 31, 2016 and 2015.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update 2014-9, *Revenue from Contracts with Customers (Topic 606)* (ASU 2014-09), to clarify the principles for recognizing revenue. This update provides a comprehensive new revenue recognition model that requires revenue to be recognized in a manner to depict the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. The original effective date would have required the Company to adopt beginning in its first quarter of fiscal 2018. In July 2015, the FASB voted to amend ASU 2014-09 by approving a one-year deferral of the effective date as well as providing the option to early adopt the standard on the original effective date. Accordingly, the Company may adopt the standard in either its first quarter of fiscal 2018 or 2019. The new revenue standard allows for either full retrospective or modified retrospective application. The Company is currently evaluating the timing of its adoption, the transition method to apply and the impact that this guidance will have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued Accounting Standards Update 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. This new standard gives a company's management the final responsibilities to decide whether there's substantial doubt about the company's ability to continue as a going concern and to provide related footnote disclosures. The standard provides guidance to management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that companies commonly provide in their footnotes. Under the new standard, management must decide whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the company's ability to continue as a going concern within one year after the date that the financial statements are issued, or within one year after the date that the financial statements are available to be issued when applicable. This guidance is effective for annual reporting ending after December 15, 2016, and interim periods thereafter, with early application permitted. Accordingly, the standard is effective for the Company on June 30, 2017. The

Table of Contents

Company has not yet completed its analysis of the impact of the adoption of this guidance. Refer to Note A, Nature of Business and Plan of Operations for further discussion.

In April 2015, the FASB issued Accounting Standards Update 2015-03, *Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. To simplify presentation of debt issuance costs, this new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by this update. This guidance is effective for annual reporting beginning after December 15, 2015, including interim periods within the year of adoption, and calls for retrospective application, with early application permitted. Accordingly, the standard is effective for the Company on July 1, 2016. The Company's consolidated balance sheet as of March 31, 2016 includes in assets \$4.7 million of debt issuance costs classified as deferred financing costs.

In July 2015, the FASB issued Accounting Standards Update 2015-11, *Simplifying the Measurement of Inventory (Topic 330)*. To simplify the principles for subsequent measurement of inventory, this new standard requires inventory measured using any method other than LIFO or the retail method shall be measured at the lower of cost and net realizable value, rather than lower of cost or market. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, and calls for prospective application, with early application permitted. Accordingly, the standard is effective for the Company on July 1, 2017. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In November 2015, the FASB issued Accounting Standards Update 2015-17, *Balance Sheet Classification of Deferred Taxes (Topic 740)*. To simplify the presentation of deferred income taxes, the amendments in this Update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. The Company implemented the recommendations of this Update prospectively, resulting in a reduction of long-term assets and current liabilities of approximately \$843,000 as of March 31, 2016. The prior period balances were not retrospectively adjusted.

In January 2016, the FASB issued Accounting Standards Update 2016-1, *Recognition and Measurement of Financial Assets and Financial Liabilities (Topic 825)*. The amendments in this Update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities (including other ownership interests, such as partnerships, unincorporated joint ventures, and limited liability companies) to be measured at fair value with changes in the fair value recognized through net income. The amendments allow equity investments that do not have readily determinable fair values to be remeasured at fair value either upon the occurrence of an observable price change or upon identification of an impairment. The amendments also require enhanced disclosures about those investments. The amendments improve financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income. This guidance is effective for annual reporting beginning after December 15, 2017, including interim periods within the year of adoption, and calls for prospective application, with early application permitted. Accordingly, the standard is effective for the Company on July 1, 2018. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update 2016-2, *Leases (Topic 842)* that primarily requires lessees to recognize most leases on their balance sheets but record expenses on their income statements in a manner similar to current accounting. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. Accordingly, the standard is effective for the Company on July 1, 2019. The Company is currently evaluating the impact of this guidance on our financial statements and the timing of adoption.

In March 2016, the FASB issued Accounting Standards Update 2016-9, *Improvements to Employee Share-Based Payment Accounting (Topic 718)* that changes the accounting for certain aspects of share-based payments to employees. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid in capital pools. The guidance also allows for the employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis. The guidance is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods with early adoption permitted. Accordingly, the standard is effective for the Company on July 1, 2017. The Company is currently evaluating the impact of this guidance on our financial statements and the timing of adoption.

Table of Contents

C. 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. Pursuant to this agreement, Roche developed and received marketing approval for its HER2-targeting ADC compound, Kadcyla, in the U.S., Europe, Japan and numerous other countries. 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, \$19.4 million of non-cash royalties on net sales of Kadcyla for the nine-month period ended December 31, 2015 were recorded and included in revenue for the nine months ended March 31, 2016 and \$13.9 million of royalties on net sales of Kadcyla for the nine-month period ended December 31, 2014 were included in royalty revenue for the nine months ended March 31, 2015. In April 2015, the Company consummated a royalty purchase transaction—see Note D below for further details. During the nine months ended March 31, 2016, \$195,000 of cash royalties were recorded resulting from an adjustment recorded in the period related to net sales of Kadcyla prior to the effective date of the royalty purchase transaction.

Amgen

Under a now-expired right-to-test agreement, in September 2009, November 2009 and December 2012, Amgen took three exclusive development and commercialization licenses. In May 2013, Amgen took one non-exclusive development and commercialization license. In October 2013, the non-exclusive license was amended and converted to an exclusive license, which Amgen sublicensed to Oxford BioTherapeutics Ltd. In December 2015, Amgen advised the Company that it had discontinued development of two product candidates, AMG 595 and AMG 172 that had been covered by two of Amgen's four exclusive licenses, and in February 2016, Amgen terminated these two licenses. For each of the two remaining development and commercialization licenses taken, 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 license are categorized as follows: development milestones \$9 million; regulatory milestones \$20 million; and sales milestones \$5 million. Amgen (or its sublicensee(s)) is responsible for the manufacturing, product development and marketing of any products resulting from these development and commercialization licenses.

In September 2015, Amgen's IND application under the remaining license not sublicensed to Oxford BioTherapeutics became effective, triggering a \$1 million milestone payment to the Company which is included in license and milestone fee revenue for the nine months ended March 31, 2016. The next potential milestone the Company will be entitled to receive under this license 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 milestone the Company will be entitled to receive under the May 2013 license will be a \$1 million development milestone for an IND becoming effective. 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 this, as well as the Company's past involvement in the research and manufacturing of these product candidates, these milestones were deemed substantive.

Sanofi

Edgar Filing: IMMUNOGEN INC - Form 10-Q

In July 2003, the Company entered into a broad collaboration agreement with Sanofi (formerly Aventis) to discover, develop and commercialize antibody-based products. The collaboration agreement provided Sanofi with worldwide development and commercialization rights to new antibody-based products directed to targets that were included in the collaboration, including the exclusive right to use the Company's maytansinoid ADC technology in the creation of products developed to these targets. No further targets may be added to this agreement and the product candidates (targets) as of March 31, 2016 in the collaboration include isatuximab (CD38), SAR566658 (CA6), SAR408701 (CEACAM5) and one undisclosed target without an associated clinical-stage product candidate.

We are entitled to receive milestone payments potentially totaling \$21.5 million, per target, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$7.5 million; and regulatory milestones \$14 million. Through March 31, 2016, the Company has received and recognized an aggregate of \$20.5 million in milestone payments for compounds covered under this agreement now or in the past, including a \$3 million development milestone related to initiation of a Phase IIb clinical trial (as defined in the agreement) for isatuximab and a \$1 million development milestone related to initiation of a Phase I clinical trial for SAR408701 which are included in license and milestone fee revenue for the nine months ended March 31, 2015. The next potential milestone the Company will be entitled to receive for each of SAR566658 and SAR408701 will be a development milestone for initiation of a Phase IIb clinical trial (as defined in the agreement), which will result in each case in a \$3 million payment being due. The next potential milestone the Company will be entitled to receive with respect to isatuximab will be a development milestone for initiation of a Phase III clinical trial, which will result in a \$3 million payment being due. The next potential milestone the Company will be entitled to receive for the unidentified target will be a development milestone

Table of Contents

for commencement of a Phase I clinical trial, which will result in a \$1 million payment being due. At the time of execution of this agreement, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's past involvement in the research and manufacturing of these product candidates, these milestones were deemed substantive.

Under a separate, now-expired right-to-test agreement, in December 2013, Sanofi took one exclusive development and commercialization license. Under this license, the Company received an exercise fee of \$2 million and is further entitled to receive up to a total of \$30 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones for each license are categorized as follows: development milestones \$10 million; and regulatory milestones \$20 million.

The Company was recognizing the \$2 million exercise fee as revenue ratably over the Company's estimated period of its substantial involvement. The Company had previously estimated this development period would conclude at the end of non-pivotal Phase II testing. During the first quarter of fiscal 2015, the Company determined it will not be substantially involved in the development and commercialization of the product based on Sanofi's current plans to develop and manufacture the product without the Company's assistance. As a result of this determination, the Company recognized the balance of the upfront exercise fee during the prior period. This change in estimate resulted in an increase to license and milestone fees of \$1.6 million for the nine months ended March 31, 2015 compared to amounts that would have been recognized pursuant to the Company's previous estimate.

Pursuant to the license agreement noted above, in October 2015, Sanofi initiated Phase I, first-in-human clinical testing of its ADC product candidate, SAR428926 (LAMP1), triggering a \$2 million development milestone payment to the Company which is included in license and milestone fee revenue for the nine months ended March 31, 2016. The next milestone payment the Company could receive would be a \$4 million development milestone for commencement of a Phase IIb clinical trial (as defined in the agreement) under this license. At the time of execution of this agreement, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's past involvement in the research and manufacturing of Sanofi's product candidates, these milestones were deemed substantive.

Bayer

In October 2008, the Company granted Bayer an exclusive development and commercialization license to the Company's ADC technology for use with antibodies or other proteins that target mesothelin. The Company received a \$4 million upfront payment upon execution of the agreement, and for each compound developed and marketed by Bayer under this collaboration the Company is entitled to receive a total of \$170.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$16 million; regulatory milestones \$44.5 million; and sales milestones \$110 million. Through March 31, 2016, the Company has received and recognized an aggregate of \$13 million in milestone payments under this agreement. In January 2016, Bayer initiated a Phase II clinical study designed to support registration of its ADC product candidate, anetumab ravtansine, triggering a \$10 million development milestone payment to the Company which is included in license and milestone fee revenue for the three and nine months ended March 31, 2016. The next potential milestone the Company will be entitled to receive will be either a \$2 million development milestone for commencement of a pivotal clinical trial for a second indication for anetumab ravtansine or a \$6 million regulatory milestone for filing of regulatory approval for its first indication for anetumab ravtansine. At the time of execution of this agreement, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's past involvement in the research and supply of cytotoxic agent for this product candidate, these milestones were deemed substantive.

Lilly

Eli Lilly and Company (Lilly) had the right to take three exclusive development and commercialization licenses under a right-to-test agreement established in December 2011, and took these licenses prior to the expiration of the agreement in December 2014. The Company received a \$20 million upfront payment in connection with the execution of the right-to-test agreement in 2011. Under the terms of this right-to-test agreement, the first license had no associated exercise fee, and the second and third licenses each had a \$2 million exercise fee. The first development and commercialization license was taken in August 2013 and the agreement was amended in December 2013 to provide Lilly with an extension provision and retrospectively include a \$2 million exercise fee for the first license in lieu of the fee due for either the second or third license. The second and third licenses were taken in December 2014, with one including the \$2 million exercise fee and the other not. Upon execution of the two licenses in December 2014, the Company recognized the remaining \$15.6 million of the \$23.5 million of arrangement consideration allocated to the development and commercialization licenses, which is included in license and milestone fee revenue for the nine months ended March 31, 2015. Under the two licenses with the \$2 million exercise fee, the Company is entitled to receive up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. Under the license taken in December 2014 without the exercise fee, 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 two development and commercialization licenses with the \$2 million exercise fee, and \$30.5 million for the one development and

Table of Contents

commercialization license with no exercise fee; regulatory milestones \$70 million in all cases; and sales milestones \$100 million in all cases.

In September 2015, Lilly initiated Phase I, first-in-human clinical testing of its ADC product candidate, LY3076226, triggering a \$5 million milestone payment to the Company which is included in license and milestone fee revenue for the nine months ended March 31, 2016. The next payment the Company could receive would be either a \$9 million milestone for commencement of a Phase II clinical trial under this license or a \$5 million development milestone payment with the commencement of a Phase I clinical trial under either of its other two licenses. At the time of execution of this agreement, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's expected involvement in the research and manufacturing of these product candidates, these milestones were 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.

Takeda

In March 2015, the Company entered into a right-to-test agreement with Takeda Pharmaceutical Company Limited (Takeda) through its wholly owned subsidiary, Millennium Pharmaceuticals, Inc. The agreement provides Takeda with the right to (a) take exclusive options, with certain restrictions, to individual targets selected by Takeda for specified option periods, (b) test the Company's ADC technology with Takeda's antibodies directed to the targets optioned under a right-to-test, or research, license, and (c) take exclusive licenses to use the Company's ADC technology to develop and commercialize products to targets optioned for up to two individual targets on terms specified in the right-to-test agreement. The Company received a \$20 million upfront payment in connection with the execution of the right-to-test agreement. Takeda must exercise its options for the development and commercialization licenses by the end of the three-year term of the right-to-test agreement, after which any then outstanding options will lapse. Takeda has the right to extend the three-year right-to-test period for one additional year by payment to the Company of \$4 million. Alternatively, Takeda has the right to expand the scope of the right-to-test agreement by payment to the Company of \$8 million. If Takeda opts to expand the scope of the right-to-test agreement, it will be entitled to take additional exclusive options, one of which may be exercised for an additional development and commercialization license, and the right-to test period will be extended until the fifth anniversary of the effective date of the right-to-test agreement. The first exclusive license was taken by Takeda in December 2015, and as a result, the Company recognized \$8.6 million of the \$25.9 million of arrangement consideration allocated to the development and commercialization licenses, which is included in license and milestone fee revenue for the nine months ended March 31, 2016. Takeda is responsible for the manufacturing, product development and marketing of any products resulting from this collaboration.

For each development and commercialization license taken, the Company is entitled to receive up to a total of \$210 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$30 million; regulatory milestones \$85 million; and sales milestones \$95 million. The first potential milestone the Company will be entitled to receive will be a \$5 million development milestone payment with the initiation of a Phase I clinical trial under the first development and commercialization license taken. 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 Takeda and research and development activities performed on behalf of Takeda.

CytomX

Edgar Filing: IMMUNOGEN INC - Form 10-Q

In January 2014, the Company entered into a reciprocal right-to-test agreement with CytomX Therapeutics, Inc. (CytomX). The agreement provides CytomX and the Company with the right to test the Company's ADC technology with CytomX masked antibodies, which it calls Probodies, to create product candidates for a specified number of targets. Each company has defined rights to test the other company's technology with its technology under a right-to-test, or research, license, and to subsequently take an exclusive, worldwide license to use the other company's technology with its technology to develop and commercialize products for the specified targets on terms agreed upon at the inception of the right-to-test agreement. The Company received no upfront cash payment in connection with the execution of the right-to-test agreement. The terms of the right-to-test agreement require the Company and CytomX to each take its respective development and commercialization licenses by the end of the term of the research licenses. In addition, both the Company and CytomX are required to perform specific research activities under the right-to-test agreement on behalf of the other party for no monetary consideration.

In February 2016, CytomX took its development and commercialization license for a specified target. An amendment of the agreement executed simultaneously with that license granted CytomX the right, for a specified period of time, to substitute the specified target with another as yet unspecified target. Accordingly, the revenue associated with this license is being deferred until the expiration of that substitution right. With respect to the development and commercialization license taken by CytomX, the Company is

Table of Contents

entitled to receive up to a total of \$160 million in milestone payments plus royalties on the commercial sales of any resulting product. The total milestones are categorized as follows: development milestones \$10 million; regulatory milestones \$50 million; and sales milestones \$100 million. In addition, CytomX may be liable to pay annual maintenance fees if the licensed product candidate covered under the development and commercialization license has not progressed to a specified stage of development within a specified time frame. Assuming no annual maintenance fee is payable, the next payment the Company could receive would be a \$1 million development milestone payment with commencement of a Phase I clinical trial. At the time of execution of the right-to-test agreement, there was significant uncertainty as to whether the milestone related to the Phase I clinical trial would be achieved. In consideration of this, as well as the Company's expected involvement in the research and manufacturing of any product candidate, this milestone was deemed substantive. CytomX is responsible for the manufacturing, product development and marketing of any product resulting from the development and commercialization license taken by CytomX under this collaboration.

D. Liability Related to Sale of Future Royalties

In April 2015, Immunity Royalty Holdings, L.P. (IRH) purchased the right to receive 100% of the royalty payments on commercial sales of Kadcyla subsequent to December 31, 2014, arising under the Company's development and commercialization license with Genentech (a unit of Roche), until IRH has received aggregate royalties equal to \$235 million or \$260 million, depending on when the aggregate royalties received by IRH reach a specified milestone. Once the applicable threshold is met, if ever, the Company will thereafter receive 85% and IRH will receive 15% of the Kadcyla royalties for the remaining royalty term. At consummation of the transaction in April 2015, the Company received cash proceeds of \$200 million. As part of this sale, the Company incurred \$5.9 million of transaction costs, which are presented in the accompanying consolidated balance sheet as deferred financing costs and will be amortized to interest expense over the estimated life of the royalty purchase agreement. Although the Company sold its rights to receive royalties from the sales of Kadcyla, as a result of its ongoing involvement in the cash flows related to these royalties, the Company will continue to account for these royalties as revenue and recorded the \$200 million in proceeds from this transaction as a liability related to sale of future royalties (Royalty Obligation) that will be amortized using the interest method over the estimated life of the royalty purchase agreement.

The following table shows the activity within the liability account during the nine-month period ended March 31, 2016 (in thousands):

	Period from June 30, 2015 to March 31, 2016
Liability related to sale of future royalties beginning balance	\$ 199,662
Non-cash Kadcyla royalty revenue	(19,355)
Non-cash interest expense recognized	14,330
Liability related to sale of future royalties ending balance	\$ 194,637

As royalties are remitted to IRH, the balance of the Royalty Obligation will be effectively repaid over the life of the agreement. Through March 31, 2016, \$24.8 million in cumulative royalty payments have been received from Roche and paid to IRH. In order to determine the amortization of the Royalty Obligation, the Company is required to estimate the total amount of future royalty payments to be received and remitted to IRH as noted above over the life of the agreement. The sum of these amounts less the \$200 million proceeds the Company received will be recorded as interest expense over the life of the Royalty Obligation. Since inception, the Company's estimate of this total interest expense resulted in an effective annual interest rate of 9.6%. The Company periodically assesses the estimated royalty payments to IRH and to the extent such payments are greater or less than its initial estimates, or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the amortization of the Royalty Obligation. There are a number of factors that could materially affect the amount and timing of royalty payments from Genentech, most of which are not within the Company's control. Such factors include, but are not

Edgar Filing: IMMUNOGEN INC - Form 10-Q

limited to, changing standards of care, the introduction of competing products, manufacturing or other delays, biosimilar competition, patent protection, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates as the royalties remitted to IRH are made in U.S. dollars (USD) while significant portions of the underlying sales of Kadcyla are made in currencies other than USD, and other events or circumstances that could result in reduced royalty payments from Kadcyla, all of which would result in a reduction of non-cash royalty revenues and the non-cash interest expense over the life of the Royalty Obligation. Conversely, if sales of Kadcyla are more than expected, the non-cash royalty revenues and the non-cash interest expense recorded by the Company would be greater over the term of the Royalty Obligation.

Table of Contents

In addition, the royalty purchase agreement grants IRH the right to receive certain reports and other information relating to the royalties and contains other representations and warranties, covenants and indemnification obligations that are customary for a transaction of this nature.

E. Capital Stock

2001 Non-Employee Director Stock Plan

During the three and nine months ended March 31, 2016, the Company recorded approximately \$(32,000) and \$(37,000) in expense reduction related to stock units outstanding under the Company's 2001 Non-Employee Director Stock Plan, or the 2001 Plan, compared to \$18,000 and \$(19,000) in expense and expense reduction recorded during the three and nine months ended March 31, 2015. 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 also entitled to receive a fixed number of stock 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 stock options in November of 2015 and 2014, respectively, and the related compensation expense for the three and nine months ended March 31, 2016 and 2015 is included in the amounts discussed in the "Stock-Based Compensation" section of footnote B above.

During the three and nine months ended March 31, 2016, the Company recorded approximately \$108,000 and \$272,000 in compensation expense, respectively, related to deferred share units issued and outstanding under the Company's Compensation Policy for Non-Employee Directors, compared to \$93,000 and \$329,000 in compensation expense recorded during the three and nine months ended March 31, 2015.

F. Commitments and Contingencies

Leases

The Company currently has a lease agreement with CRP/King 830 Winter L.L.C. for the rental of approximately 110,000 square feet of laboratory and office space at 830 Winter Street, Waltham, MA through March 2026. The Company uses this space for its corporate headquarters and other operations. The Company may extend the lease for two additional terms of five years. Pursuant to lease amendments executed in December 2013 and April 2014, the Company received construction allowances of approximately \$746,000 and \$1.1 million, respectively, to build out office and lab space to the Company's specifications, and will receive up to \$196,000 as a construction allowance pursuant to an amendment executed in December 2015. 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.

In February 2016, the Company entered into a lease agreement with PDM 930 Unit, LLC for the rental of 10,281 square feet of additional office space at 930 Winter Street, Waltham, MA. The term of the lease is for five years and two months commencing upon delivery of the premises to the Company for its use which is anticipated to be approximately May 1, 2016. The Company will receive up to approximately \$617,000 as a construction allowance to build out the office space to the Company's specifications. The Company is required to pay certain operating expenses for the leased premises based on its pro-rata share of such expenses for the entire rentable space of the building.

The Company also leases manufacturing and office space at 333 Providence Highway, Norwood, MA under an agreement through 2018 with an option to extend the lease for an additional term of five years. The Company is required to pay certain operating expenses for the leased premises subject to escalation charges for certain expense increases over a base amount.

Table of Contents

Effective April 2013, the Company entered into a lease agreement with River Ridge Limited Partnership for the rental of 7,507 square feet of additional office space at 100 River Ridge Drive, Norwood, MA. The initial term of the lease is for five years and two months commencing in July 2013 with an option for the Company to extend the lease for an additional term of five years. The Company is required to pay certain operating expenses for the leased premises subject to escalation charges for certain expense increases over a base amount. The Company entered into a sublease in December 2014 for this space, effective from January 2015 through July 2018.

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):

2016 (three months remaining)	\$	1,859
2017		7,876
2018		7,995
2019		7,197
2020		7,193
Thereafter		41,163
Total minimum lease payments	\$	73,283
Total minimum rental payments from sublease		(280)
Total minimum lease payments, net	\$	73,003

There are no obligations under capital leases as of March 31, 2016, as all of the capital leases were single payment obligations which have all been made.

Collaborations

The Company is contractually obligated to make potential future success-based development, regulatory or sales milestone payments in conjunction with certain collaborative agreements. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, the Company may be required to pay such amounts. Further, the timing of any future payment is not reasonably estimable. As of March 31, 2016, the maximum amount that may be payable in the future under the Company's current collaborative agreements is \$162 million, \$1.4 million of which is reimbursable by a third party under a separate agreement.

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

Since our inception, we have been principally engaged in the development of targeted anticancer agents referred to as antibody-drug conjugates, or ADCs. An ADC with our technology consists of a manufactured antibody that binds specifically to an antigen target found on the surface of

cancer cells with one of our proprietary, highly potent cancer-killing agents attached. Its antibody component enables an ADC compound to bind specifically to a tumor cell with the target antigen on its surface, which the cancer-killing agent can then kill. The cancer-killing agent is attached to the antibody using one of our engineered linkers, which control the release and activation of the cancer-killing agent inside the tumor 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. Our lead ADC product candidates employ either DM1 or DM4 as the cancer-killing agent. Both DM1 and DM4, collectively DMx, are our proprietary derivatives of maytansine and kill tumor cells by disrupting a process, tubulin formation, the cancer cells undergo more frequently than most healthy cells. We also have developed DNA-alkylating agents that we call IGNs. Our IMGN779 ADC is the most advanced IGN-utilizing ADC.

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

Table of Contents

future will result from payments under our collaborative arrangements. In addition to the discussion below for certain agreements, details for all of our significant agreements can be found in our 2015 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. Pursuant to this agreement, Roche developed and received marketing approval for its HER2-targeting ADC compound, Kadcyla, in the U.S., Europe, Japan and numerous other countries. We receive royalty reports and payments related to sales of Kadcyla from Roche one quarter in arrears. In accordance with our revenue recognition policy, \$19.4 million of non-cash royalties on net sales of Kadcyla for the nine-month period ended December 31, 2015 were recorded and included in revenue for the nine months ended March 31, 2016 and \$13.9 million of royalties on net sales of Kadcyla for the nine-month period ended December 31, 2015 were included in royalty revenue for the nine months ended March 31, 2015. In April 2015, we consummated a royalty purchase transaction – see Liquidity and Capital Resources below for further details. During the three months ended March 31, 2016, we recorded \$195,000 of cash royalties resulting from an adjustment recorded in the current period related to net sales of Kadcyla prior to the effective date of the royalty purchase transaction.

Amgen Under a now-expired right-to-test agreement, in December 2012, Amgen took an exclusive development and commercialization license. 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 from this license. The total milestones are categorized as follows: development milestones \$9 million; regulatory milestones \$20 million; and sales milestones \$5 million. In September 2015, the IND application for its ADC product candidate under this license became effective, triggering a \$1 million milestone payment to us which is included in license and milestone fee revenue for the nine months ended March 31, 2016.

In December 2015, Amgen advised the Company that it had discontinued development of two product candidates, AMG 595 and AMG 172 that had been covered by two of Amgen's four exclusive licenses and in February 2016, Amgen terminated these two licenses.

Sanofi In July 2003, we entered into a broad collaboration agreement with Sanofi (formerly Aventis) to discover, develop and commercialize antibody-based products. The collaboration agreement provided Sanofi with worldwide development and commercialization rights to new antibody-based products directed to targets that were included in the collaboration, including the exclusive right to use our maytansinoid ADC technology in the creation of products developed to these targets. No further targets may be added to this agreement and the product candidates (targets) as of March 31, 2016 in the collaboration include isatuximab (CD38), SAR566658 (CA6), SAR408701 (CEACAM5) and one undisclosed target without an associated clinical-stage product candidate.

We are entitled to receive milestone payments potentially totaling \$21.5 million, per target, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$7.5 million; and regulatory milestones \$14 million. Through March 31, 2016, we have received and recognized an aggregate of \$20.5 million in milestone payments for compounds covered under

this agreement now or in the past, including a \$3 million development milestone related to initiation of a Phase IIb clinical trial (as defined in the agreement) for isatuximab and a \$1 million development milestone related to initiation of a Phase I clinical trial for SAR408701 which are included in license and milestone fee revenue for the nine months ended March 31, 2015.

Under a separate, now-expired right-to-test agreement, in December 2013, Sanofi took one exclusive development and commercialization license. Under this license, we received an exercise fee of \$2 million and are further entitled to receive 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.

The Company was recognizing the \$2 million exercise fee as revenue ratably over our estimated period of its substantial involvement. We had previously estimated this development period would conclude at the end of non-pivotal Phase II testing. During the first quarter of fiscal 2015, we determined we will not be substantially involved in the development and commercialization of the product based on Sanofi's current plans to develop and manufacture the product without our assistance. As a result of this determination, we recognized the balance of the upfront exercise fee during the prior period. This change in estimate resulted in an increase to license and milestone fees of \$1.6 million for the nine months ended March 31, 2015 compared to amounts that would have been recognized pursuant to our previous estimate. Pursuant to this license agreement, in October 2015, Sanofi initiated Phase I, first-in-human clinical testing of its ADC product candidate, SAR428926 (LAMP1), triggering a \$2 million development milestone payment to us which is included in license and milestone fee revenue for the nine months ended March 31, 2016.

Bayer

In October 2008, we granted Bayer an exclusive development and commercialization license to our ADC technology for use with antibodies or other proteins that target mesothelin. We received a \$4 million upfront payment upon execution of the agreement,

Table of Contents

and for each compound developed and marketed by Bayer under this collaboration we are entitled to receive a total of \$170.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$16 million; regulatory milestones \$44.5 million; and sales milestones \$110 million. Through March 31, 2016, we have received and recognized an aggregate of \$13 million in milestone payments under this agreement. In January 2016, Bayer initiated a Phase II clinical study designed to support registration of its ADC product candidate, anetumab ravtansine, triggering a \$10 million development milestone payment to us which is included in license and milestone fee revenue for the three and nine months ended March 31, 2016.

Lilly Under a now-expired right-to-test agreement executed in December 2011, Lilly has taken three exclusive development and commercialization licenses. We 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, we received an exercise fee in the amount of \$2 million and are entitled to receive up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. The second and third exclusive licenses were taken in December 2014, one of which we received an exercise fee in the amount of \$2 million and are entitled to receive up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. For the third license taken in December 2014, for which we did not receive an exercise fee, 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 two development and commercialization licenses with the \$2 million exercise fee, and \$30.5 million for the one development and commercialization license with no exercise fee; regulatory milestones \$70 million in all cases; and sales milestones \$100 million in all cases. In September 2015, Lilly began Phase I evaluation of one of their potential products which triggered a \$5 million milestone payment to us which is included in license and milestone fee revenue for the nine months ended March 31, 2016.

Takeda In March 2015, we entered into a right-to-test agreement with Takeda Pharmaceutical Company Limited (Takeda) through its wholly owned subsidiary, Millennium Pharmaceuticals, Inc. We received a \$20 million upfront payment in connection with the execution of the right-to-test agreement. Takeda must exercise its options for the development and commercialization licenses by the end of the three-year term of the right-to-test agreement, after which any then outstanding options will lapse. Takeda has the right to extend the three-year right-to-test period for one additional year by payment to us of \$4 million. Alternatively, Takeda has the right to expand the scope of the right-to-test agreement by payment to us of \$8 million. If Takeda opts to expand the scope of the right-to-test agreement, it will be entitled to take additional exclusive options, one of which may be exercised for an additional development and commercialization license, and the right-to test period will be extended until the fifth anniversary of the effective date of the right-to-test agreement. The first exclusive license was taken by Takeda in December 2015, and as a result, we recognized \$8.6 million of the \$25.9 million of arrangement consideration allocated to the development and commercialization licenses, which is included in license and milestone fee revenue for the nine months ended March 31, 2016. For each development and commercialization license taken, we are entitled to receive up to a total of \$210 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones \$30 million; regulatory milestones \$85 million; and sales milestones \$95 million.

CytomX In January 2014, we entered into a reciprocal right-to-test agreement with CytomX Therapeutics, Inc. (CytomX). The agreement provides CytomX and us with the right to test our ADC technology with CytomX masked

antibodies, which it calls Probodies , to create product candidates for a specified number of targets. Each company has defined rights to test the other company s technology with its technology under a right-to-test, or research, license, and to subsequently take an exclusive, worldwide license to use the other Company s technology with its technology to develop and commercialize products for the specified targets on terms agreed upon at the inception of the right-to-test agreement. We received no upfront cash payment in connection with the execution of the right-to-test agreement. The terms of the right-to-test agreement require us and CytomX to each take its respective development and commercialization licenses by the end of the term of the research licenses. In addition, both we and CytomX are required to perform specific research activities under the right-to-test agreement on behalf of the other party for no monetary consideration.

In February 2016, CytomX took its development and commercialization license for a specified target. An amendment of the agreement executed simultaneously with that license granted CytomX the right, for a specified period of time, to substitute the target with another as yet unspecified target. Accordingly, the revenue associated with this license is being deferred until the expiration of that substitution right. With respect to the development and commercialization license taken by CytomX, we are entitled to receive up to a total of \$160 million in milestone payments plus royalties on the commercial sales of any resulting product. The total milestones are categorized as follows: development milestones \$10 million; regulatory milestones \$50 million; and sales milestones \$100 million.

To date, we have not generated revenues from commercial sales of internal products and we expect to incur significant operating losses for the foreseeable future. As of March 31, 2016, we had approximately \$182.9 million in cash and cash equivalents compared to \$278.1 million in cash and cash equivalents as of June 30, 2015.

Table of Contents

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

Non-Cash Interest Expense on Liability Related to Sale of Future Royalty

In April 2015, Immunity Royalty Holdings, L.P. (IRH) purchased our right to receive 100% of the royalty payments on commercial sales of Kadcyla subsequent to December 31, 2014, arising under our development and commercialization license with Genentech, until IRH has received aggregate royalties equal to \$235 million or \$260 million, depending on when the aggregate royalties received by IRH reach a specified milestone. As described in Note D to our Consolidated Financial Statements, this royalty sale transaction has been recorded as a liability that amortizes over the estimated royalty payment period as Kadcyla royalties are remitted directly to the purchaser. We impute interest on the transaction and record interest expense at the effective interest rate, which we currently estimate to be 9.6%. There are a number of factors that could materially affect the estimated interest rate, in particular, the amount and timing of royalty payments from future net sales of Kadcyla, and we will assess this estimate on a periodic basis. As a result, future interest rates could differ significantly and any such change in interest rate will be adjusted prospectively.

Critical Accounting Policies

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

There were no significant changes to our critical accounting policies from those disclosed in our Annual Report on Form 10-K for the fiscal year ended June 30, 2015.

RESULTS OF OPERATIONS

Comparison of Three Months ended March 31, 2016 and 2015

Revenues

Our total revenues for the three months ended March 31, 2016 and 2015 were \$19.7 million and \$11.4 million, respectively. The \$8.3 million increase in revenues in the three months ended March 31, 2016 from the same period in the prior year is attributable to an increase in all revenue categories, all of which are discussed below.

Revenues from license and milestone fees for the three months ended March 31, 2016 increased \$5.0 million to \$10.1 million from \$5.1 million in the same period ended March 31, 2015. Included in license and milestone fees for the three months ended March 31, 2016 is a \$10 million development milestone achieved under a license agreement with Bayer. Included in license and milestone fees for the three months ended March 31, 2015 is a \$5 million development milestone achieved under a license agreement with Novartis. 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 March 31, 2016 and 2015 is included in the following table (in thousands):

Table of Contents

License and Milestone Fees	Three Months Ended March 31,	
	2016	2015
Collaborative Partner:		
Amgen	\$ 4	\$ 4
Bayer	10,000	
Biotest		7
Lilly	6	6
Novartis	45	5,045
Sanofi	1	16
Takeda	21	
Total	\$ 10,077	\$ 5,078

Deferred revenue of \$32.4 million as of March 31, 2016 primarily represents consideration received from our collaborators pursuant to our license agreements, which we have yet to earn pursuant to our revenue recognition policy. Included within this amount is \$13 million of non-cash consideration recorded in connection with our arrangement with CytomX during fiscal 2014.

Kadcyla is an ADC marketed 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 Kadcyla from Roche one quarter in arrears. In accordance with our revenue recognition policy, \$7.4 million of non-cash royalties on net sales of Kadcyla for the three-month period ended December 31, 2015 were recorded and included in revenue for the three months ended March 31, 2016 and \$5.1 million of royalties on net sales of Kadcyla for the three-month period ended December 31, 2014 is included in revenue for the three months ended March 31, 2015. We expect non-cash royalty revenue to increase in future periods as the underlying net sales of Kadcyla increase. In April 2015, we consummated a royalty purchase transaction – see Liquidity and Capital Resources below for further details.

Research and development support revenue was \$1.1 million for the three months ended March 31, 2016 compared with \$532,000 for the three months ended March 31, 2015. 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 three-month periods ended March 31, 2016 and 2015 is included in the following table (in thousands):

Research and Development Support	Three Months Ended March 31,	
	2016	2015
Collaborative Partner:		
Amgen	\$	\$ 59
Biotest	77	278
CytomX	565	9
Lilly	127	137
Novartis	31	20
Takeda	185	12
Other	74	17
Total	\$ 1,059	\$ 532

Edgar Filing: IMMUNOGEN INC - Form 10-Q

Clinical materials revenue was \$1.2 million for the three months ended March 31, 2016 compared with \$718,000 for the three months ended March 31, 2015. 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.

Table of Contents*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 March 31, 2016 increased \$10.4 million to \$36.1 million from \$25.7 million for the three months ended March 31, 2015. A more detailed discussion of research and development expense in the period follows.

We are unable to accurately estimate which potential product candidates, if any, will eventually move into our internal preclinical research program. We are unable to reliably estimate the costs to develop these products as a result of the uncertainties related to discovery research efforts as well as preclinical and clinical testing. Our decision to move a product candidate into the clinical development phase is predicated upon the results of preclinical tests. We cannot accurately predict which, if any, of the discovery stage product candidates will advance from preclinical testing and move into our internal clinical development program. The clinical trial and regulatory approval processes for our product candidates that have advanced or that we intend to advance to clinical testing are lengthy, expensive and uncertain in both timing and outcome. 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 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 March 31,	
	2016	2015
Research	\$ 6,285	\$ 5,721
Preclinical and Clinical Testing	16,390	9,941
Process and Product Development	3,437	2,138
Manufacturing Operations	9,982	7,866

Edgar Filing: IMMUNOGEN INC - Form 10-Q

Total Research and Development Expense	\$	36,094	\$	25,666
--	----	--------	----	--------

Research: Research includes expenses primarily associated with activities to identify and evaluate new targets and to develop and evaluate new antibodies, linkers and cytotoxic agents for our products and in support of our collaborators. Such expenses primarily include personnel, contract services, research licensing fees, facilities and lab supplies. Research expenses for the three months ended March 31, 2016 increased \$564,000 compared to the three months ended March 31, 2015. This increase is principally due to an increase in salaries and related expenses driven primarily by increases in personnel and an increase in lab supplies driven by increased activities. We expect research expenses for fiscal 2016 to be higher than fiscal 2015 due to increases in personnel and lab supplies to support internal and partner efforts.

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 March 31, 2016 increased \$6.5 million to \$16.4 million compared to \$9.9 million for the three months ended March 31, 2015. This increase is primarily the result of an increase in contract service

Table of Contents

expense and clinical trial expense driven primarily by increased activities related to mirvetuximab ravtansine, and to a lesser extent, increased activities related to IMGN529 and IMGN779. Salaries and related expenses also increased due primarily to increases in personnel to support internal program advancement. We expect preclinical and clinical testing expenses for fiscal 2016 to be significantly higher than fiscal 2015 driven primarily by increased activities to advance our wholly owned product candidates, mirvetuximab ravtansine and IMGN529, to later-stage clinical testing, and IMGN779 to Phase I clinical testing.

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 March 31, 2016, total development expenses increased \$1.3 million compared to the three months ended March 31, 2015. This increase is principally due to an increase in salaries and related expenses driven primarily by increases in personnel and an increase in contract services driven by increased development activities related to our IGN cytotoxic agents. We expect process and product development expenses for fiscal 2016 to be significantly higher than fiscal 2015 due to increases in personnel to support internal and partner efforts and increases in contract services to support further development of our IGN cytotoxic agents.

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 three months ended March 31, 2016, manufacturing operations expense increased \$2.1 million to \$10.0 million compared to \$7.9 million in the same period last year. The increase in the three months ended March 31, 2016 as compared to the three months ended March 31, 2015 is principally the result of (i) an increase in cost of clinical materials revenue charged to research and development expense due to timing of orders of such clinical materials from our partners; (ii) a decrease in costs capitalized into inventory due to a lesser number of manufactured batches of conjugated materials on behalf of our collaborators; and (iii) an increase in salaries and related expenses driven primarily by increases in personnel. We expect manufacturing operations expense for fiscal 2016 to be higher than fiscal 2015 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 March 31, 2016 increased \$4.2 million compared to the same period last year. This increase is primarily due to a \$2.8 million stock compensation charge incurred during the current period related to the modification of the terms of certain options previously granted to the CEO of the Company in connection with his planned retirement from the Company and an increase in salaries and related expenses driven by additional personnel, and to a lesser extent, an increase in professional fees and contract services. We expect general and administrative expenses for fiscal 2016 to be higher than fiscal 2015 due primarily to increased salaries and related expenses, including the CEO-related stock compensation charge, and increased professional fees.

Investment Income, net

Investment income for the three months ended March 31, 2016 and 2015 was \$108,000 and \$14,000, respectively. The increase in the current period is due to a greater average cash balance attributable to receipt of \$200 million of gross proceeds in April 2015 upon consummation of the royalty purchase agreement with Immunity Royalty Holdings, L.P.

Table of Contents

Non-Cash Interest Expense on Liability Related to Sale of Future Royalty

In April 2015, Immunity Royalty Holdings, L.P. (IRH) purchased our right to receive 100% of the royalty payments on commercial sales of Kadcyla subsequent to March 31, 2014, arising under our development and commercialization license with Genentech, until IRH has received aggregate royalties equal to \$235 million or \$260 million, depending on when the aggregate royalties received by IRH reach a specified milestone. As described in Note D to our Consolidated Financial Statements, this royalty sale transaction has been recorded as a liability that amortizes over the estimated royalty payment period as Kadcyla royalties are remitted directly to the purchaser. During the three months ended March 31, 2016, we recorded \$5.0 million of non-cash interest expense which includes amortization of deferred financing costs. We impute interest on the transaction and record interest expense at the effective interest rate, which we currently estimate to be 9.6%. There are a number of factors that could materially affect the estimated interest rate, in particular, the amount and timing of royalty payments from future net sales of Kadcyla, and we will assess this estimate on a periodic basis. As a result, future interest rates could differ significantly and any such change in interest rate will be adjusted prospectively.

Other Income (Expense), net

Other income (expense), net for the three months ended March 31, 2016 and 2015 was \$551,000 and \$(393,000), respectively. We incurred \$548,000 and \$(393,000) in foreign currency exchange gains (losses) related to obligations with non-U.S. dollar-based suppliers and Euro cash balances maintained to fulfill them during the three months ended March 31, 2016 and 2015, respectively.

Comparison of Nine Months ended March 31, 2016 and 2015

Revenues

Our total revenues for the nine months ended March 31, 2016 and 2015 were \$52.6 million and \$72.9 million, respectively. The \$20.3 million decrease in revenues in the nine months ended March 31, 2016 from the same period in the prior year is attributable to a decrease in license and milestone fees and clinical materials revenue, partially offset by an increase in royalty revenue and research and development support revenue, all of which are discussed below.

Revenues from license and milestone fees for the nine months ended March 31, 2016 decreased \$25.9 million to \$26.8 million from \$52.7 million in the same period ended March 31, 2015. Included in license and milestone fees for the nine months ended March 31, 2016 is \$8.6 million of license revenue earned upon the execution of a development and commercialization license taken by Takeda, a \$5 million development milestone achieved under a license agreement with Lilly, a \$1 million development milestone achieved under a license agreement with Amgen, a \$2 million development milestone achieved under a license agreement with Sanofi and a \$10 million development milestone achieved under a license agreement with Bayer. Included in license and milestone fees for the nine months ended March 31, 2015 is \$15.6 million of license revenue earned upon the execution of two development and commercialization licenses by Lilly, \$25.7 million of license revenue earned upon the execution of three development and commercialization licenses by Novartis, a \$5 million development milestone achieved under one of the development

and commercialization licenses with Novartis and \$4 million in development milestones achieved under our collaboration agreement with Sanofi. Also, during the prior-year period, we made a change in estimate to our period of substantial involvement as it relates to an exclusive license with Sanofi which resulted in an increase to license and milestone fees of \$1.6 million for the prior period compared to amounts that would have been recognized pursuant to the Company's previous estimate. 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 nine-month periods ended March 31, 2016 and 2015 is included in the following table (in thousands):

License and Milestone Fees Collaborative Partner:	Nine Months Ended March 31,	
	2016	2015
Amgen	\$ 1,013	\$ 13
Bayer	10,000	
Biotest	12	19
Janssen		241
Lilly	5,017	15,639
Novartis	135	30,869
Sanofi	2,009	5,948
Takeda	8,653	
Total	\$ 26,839	\$ 52,729

Table of Contents

Kadcyla is an ADC marketed 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 Kadcyla from Roche one quarter in arrears. In accordance with our revenue recognition policy, \$19.4 million of non-cash royalties on net sales of Kadcyla for the nine-month period ended December 31, 2015 were recorded and included in revenue for the nine months ended March 31, 2016 and \$13.9 million of royalties on net sales of Kadcyla for the nine-month period ended December 31, 2014 is included in revenue for the nine months ended March 31, 2015. We expect non-cash royalty revenue to increase in future periods as the underlying net sales of Kadcyla increase. In April 2015, we consummated a royalty purchase transaction – see Liquidity and Capital Resources below for further details. During the nine months ended March 31, 2016, we recorded \$195,000 of cash royalties resulting from an adjustment recorded in the current period related to net sales of Kadcyla prior to the effective date of the royalty purchase transaction.

Research and development support revenue was \$2.7 million for the nine months ended March 31, 2016 and \$2.1 million for the nine months ended March 31, 2015. 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 nine-month periods ended March 31, 2016 and 2015 is included in the following table (in thousands):

Research and Development Support Collaborative Partner:	Nine Months Ended March 31,	
	2016	2015
Amgen	\$ 30	\$ 97
Biotest	297	458
CytomX	912	49
Lilly	388	1,010
Novartis	130	476
Takeda	846	12
Other	76	38
Total	\$ 2,679	\$ 2,140

Clinical materials revenue was \$3.5 million for the nine months ended March 31, 2016 compared with \$4.2 million for the nine months ended March 31, 2015. 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 nine months ended March 31, 2016 increased \$28.1 million to \$109.4 million from \$81.3 million for the nine months ended March 31, 2015. A more detailed discussion of research and development expense in the period follows.

We are unable to accurately estimate which potential product candidates, if any, will eventually move into our internal preclinical research program. We are unable to reliably estimate the costs to develop these products as a result of the uncertainties related to discovery research efforts as well as preclinical and clinical testing. Our decision to move a product candidate into the clinical development phase is predicated upon the results of preclinical tests. We cannot accurately predict which, if any, of the discovery stage product candidates will advance from preclinical testing and move into our internal clinical development program. The clinical trial and regulatory approval processes for our product candidates that have advanced or that we intend to advance to clinical testing are lengthy, expensive and uncertain in both timing and outcome. 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

Table of Contents

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 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	Nine Months Ended March 31,	
	2016	2015
Research	\$ 18,188	\$ 15,313
Preclinical and Clinical Testing	49,921	31,157
Process and Product Development	9,019	6,382
Manufacturing Operations	32,297	28,479
Total Research and Development Expense	\$ 109,425	\$ 81,331

Research: Research includes expenses primarily associated with activities to identify and evaluate new targets and to develop and evaluate new antibodies, linkers and cytotoxic agents for our products and in support of our collaborators. Such expenses primarily include personnel, contract services, research licensing fees, facilities and lab supplies. Research expenses for the nine months ended March 31, 2016 increased \$2.9 million compared to the nine months ended March 31, 2015. This increase is principally due to an increase in salaries and related expenses driven primarily by increases in personnel, and to a lesser extent, an increase in lab supplies driven by increased activity. We expect research expenses for fiscal 2016 to be higher than fiscal 2015 due primarily to increases in personnel and lab supplies to support internal and partner efforts.

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 nine months ended March 31, 2016 increased \$18.7 million to \$49.9 million compared to \$31.2 million for the nine months ended March 31, 2015. This increase is primarily the result of an increase in contract service expense and clinical trial expense driven primarily by

increased activities related to mirvetuximab ravtansine, and to a lesser extent, increased activities related to IMG529 and IMG779. Salaries and related expenses also increased due primarily to increases in personnel to support internal program advancement. We expect preclinical and clinical testing expenses for fiscal 2016 to be significantly higher than fiscal 2015 driven primarily by increased activities to advance our wholly owned product candidates, mirvetuximab ravtansine and IMG529, to later-stage clinical testing, as well as IMG779 to Phase I clinical testing.

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 nine months ended March 31, 2016, total development expenses increased \$2.6 million compared to the nine months ended March 31, 2015. This increase is principally due to an increase in salaries and related expenses driven primarily by increases in personnel and an increase in contract services driven by increased development activities related to our IGN cytotoxic agents. We expect process and product development expenses for fiscal 2016 to be significantly higher than fiscal 2015 due to increases in personnel to support internal and partner efforts and increases in contract services to support further development of our IGN cytotoxic agents.

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

Table of Contents

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 nine months ended March 31, 2016, manufacturing operations expense increased \$3.8 million to \$32.3 million compared to \$28.5 million in the same period last year. This increase is principally the result of an increase in antibody development and supply costs driven primarily by timing of supply requirements for our mirvetuximab soravtansine and coltuximab programs, partially offset by costs incurred in the prior year period related to IMGN289 development activities. The increase is also a result of a decrease in costs capitalized into inventory due to a lesser number of manufactured batches of conjugated materials on behalf of our collaborators. We expect manufacturing operations expense for fiscal 2016 to be higher than fiscal 2015 due primarily to increased activities to advance our wholly owned product candidates.

General and Administrative Expenses

General and administrative expenses for the nine months ended March 31, 2016 increased \$6.7 million compared to the same period last year. This increase is primarily due to a \$2.8 million stock compensation charge incurred during the current period related to the modification of the terms of certain options previously granted to the CEO of the Company in connection with his planned retirement from the Company and an increase in salaries and related expenses driven by additional personnel, and to a lesser extent, an increase in professional fees and contract services. We expect general and administrative expenses for fiscal 2016 to be higher than fiscal 2015 due primarily to increased salaries and related expenses, including the CEO-related stock compensation charge, and increased professional fees.

Investment Income, net

Investment income for the nine months ended March 31, 2016 and 2015 was \$219,000 and \$36,000, respectively. The increase in the current period is due to greater average cash balance attributable to receipt of \$200 million of gross proceeds in April 2015 upon consummation of the royalty purchase agreement with Immunity Royalty Holdings, L.P.

Non-Cash Interest Expense on Liability Related to Sale of Future Royalty

In April 2015, Immunity Royalty Holdings, L.P. (IRH) purchased our right to receive 100% of the royalty payments on commercial sales of Kadcyla subsequent to December 31, 2014, arising under our development and commercialization license with Genentech, until IRH has received aggregate royalties equal to \$235 million or \$260 million, depending on when the aggregate royalties received by IRH reach a specified milestone. As described in Note C to our Consolidated Financial Statements, this royalty sale transaction has been recorded as a liability that amortizes over the estimated royalty payment period as Kadcyla royalties are remitted directly to the purchaser. During the nine months ended March 31, 2016, we recorded \$15.2 million of non-cash interest expense which includes amortization of deferred financing costs. We impute interest on the transaction and record interest expense at the effective interest rate, which we currently estimate to be 9.6%. There are a number of factors that could materially affect the estimated interest rate, in particular, the amount and timing of royalty payments from future net sales of Kadcyla, and we will assess this estimate on a periodic basis. As a result, future interest rates could differ significantly and any such change in interest rate will be adjusted prospectively.

Other Income (Expense), net

Other income (expense), net for the nine months ended March 31, 2016 and 2015 was \$509,000 and \$(933,000), respectively. We incurred \$480,000 and \$(940,000) in foreign currency exchange gains (losses) related to obligations with non-U.S. dollar-based suppliers and Euro cash balances maintained to fulfill them during the nine months ended March 31, 2016 and 2015, respectively.

LIQUIDITY AND CAPITAL RESOURCES

	March 31, 2016	As of June 30, 2015
	(In thousands)	
Cash and cash equivalents	\$ 182,913	\$ 278,109
Shareholders' equity	(41,143)	35,104

	Nine Months Ended March 31, 2016	2015
	(In thousands)	
Cash used for operating activities	\$ (91,569)	\$ (26,838)
Cash used for investing activities	(8,606)	(5,028)
Cash provided by financing activities	4,979	1,432

Table of Contents

Cash Flows

We require cash to fund our operating expenses, including the advancement of our own clinical programs, and to make capital expenditures. Historically, we have funded our cash requirements primarily through equity financings in public markets and payments from our collaborators, including license fees, milestones, research funding and more recently, royalties. We have also sold our rights to receive royalties on Kadcyla for up-front consideration. As of March 31, 2016, we had approximately \$182.9 million in cash and cash equivalents. Net cash used for operations was \$91.6 million and \$26.8 million for the nine months ended March 31, 2016 and 2015, respectively. The principal use of cash for operating activities for both periods presented was to fund our net loss. The prior year period benefited from a \$20 million upfront payment received in connection with the execution of the right-to-test agreement with Takeda in March 2015, as well as lower operating expenses.

Net cash used for investing activities was \$8.6 million and \$5.0 million for the nine months ended March 31, 2016 and 2015, respectively, and represents cash outflows for capital expenditures, primarily for the purchase of new equipment and leasehold improvements.

Net cash provided by financing activities was \$5.0 million and \$1.4 million for the nine months ended March 31, 2016 and 2015, respectively, which represents proceeds from the exercise of approximately 498,000 and 205,000 stock options, respectively.

In March 2015, we entered into a royalty purchase agreement with Immunity Royalty Holdings, L.P., which became effective on April 3, 2015, pursuant to which Immunity Royalty Holdings purchased our right to receive 100% of the royalty payments on commercial sales of Kadcyla® subsequent to December 31, 2014, arising under our License Agreement with Genentech, Inc. dated as of May 2, 2000, as amended, until Immunity Royalty Holdings has received aggregate Kadcyla royalties equal to \$235 million or \$260 million, depending on when the aggregate Kadcyla royalties received by Immunity Royalty Holdings reach a specified milestone. Once the applicable threshold is met, if ever, we will thereafter receive 85% and Immunity Royalty Holdings will receive 15% of the Kadcyla royalties for the remaining royalty term. At consummation of the transaction in April 2015, we received gross cash proceeds of \$200 million. The Company recorded these cash proceeds as a deferred royalty obligation liability which will be amortized over the expected royalty recovery period. As part of this transaction, the Company incurred approximately \$5.9 million in transaction costs.

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 through fiscal year 2017. 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. Such strategic partner transactions and alternative financing arrangements may not be available when required or may not be available on favorable terms. See Note A of the consolidated financial statements for further discussion.

Contractual Obligations

Edgar Filing: IMMUNOGEN INC - Form 10-Q

There have been no material changes to our contractual obligations during the current period from those disclosed in our Annual Report on Form 10-K for the fiscal year ended June 30, 2015.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update 2014-9, *Revenue from Contracts with Customers (Topic 606)*, to clarify the principles for recognizing revenue. This update provides a comprehensive new revenue recognition model that requires revenue to be recognized in a manner to depict the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. The original effective date would have required us to adopt beginning in our first quarter of fiscal 2018. In July 2015, the FASB voted to amend ASU 2014-09 by approving a one-year deferral of the effective date as well as providing the option to early adopt the standard on the original effective date. Accordingly, the Company may adopt the standard in either its first quarter of fiscal 2018 or 2019. The new revenue standard allows for either full retrospective or modified retrospective application. We are currently evaluating the timing of its adoption, the transition method to apply and the impact that this guidance will have on our financial statements and related disclosures.

In August 2014, the FASB issued Accounting Standards Update 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. This new standard gives a company's management the final responsibilities to decide whether there's substantial doubt about the company's ability to

Table of Contents

continue as a going concern and to provide related footnote disclosures. The standard provides guidance to management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that companies commonly provide in their footnotes. Under the new standard, management must decide whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the company's ability to continue as a going concern within one year after the date that the financial statements are issued, or within one year after the date that the financial statements are available to be issued when applicable. This guidance is effective for annual reporting ending after December 15, 2016, and interim periods thereafter, with early application permitted. Accordingly, the standard is effective for us on June 30, 2017. We have not yet completed our analysis of the impact of the adoption of this guidance. Refer to Note A, Nature of Business and Plan of Operations, of our consolidated financial statements for further discussion.

In April 2015, the FASB issued Accounting Standards Update 2015-03, *Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. To simplify presentation of debt issuance costs, this new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by this update. This guidance is effective for annual reporting beginning after December 15, 2015, including interim periods within the year of adoption, and calls for retrospective application, with early application permitted. Accordingly, the standard is effective for us on July 1, 2016. Our consolidated balance sheet as of March 31, 2016 includes in assets \$4.7 million of debt issuance costs classified as deferred financing costs.

In November 2015, the FASB issued Accounting Standards Update 2015-17, *Balance Sheet Classification of Deferred Taxes (Topic 740)*. To simplify the presentation of deferred income taxes, the amendments in this Update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. We implemented the recommendations of this Update prospectively, resulting in a reduction of long-term assets and current liabilities of approximately \$843,000 as of March 31, 2016. The prior period balances were not retrospectively adjusted.

In January 2016, the FASB issued Accounting Standards Update 2016-1, *Recognition and Measurement of Financial Assets and Financial Liabilities (Topic 825)*. The amendments in this Update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities (including other ownership interests, such as partnerships, unincorporated joint ventures, and limited liability companies) to be measured at fair value with changes in the fair value recognized through net income. The amendments allow equity investments that do not have readily determinable fair values to be remeasured at fair value either upon the occurrence of an observable price change or upon identification of an impairment. The amendments also require enhanced disclosures about those investments. The amendments improve financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income. This guidance is effective for annual reporting beginning after December 15, 2017, including interim periods within the year of adoption, and calls for prospective application, with early application permitted. Accordingly, the standard is effective for us on July 1, 2018. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update 2016-2, *Leases (Topic 842)* that primarily requires lessees to recognize most leases on their balance sheets but record expenses on their income statements in a manner similar to current accounting. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. Accordingly, the standard is effective for us on July 1, 2019. We are currently evaluating the impact of this guidance on our financial statements and the timing of adoption.

Edgar Filing: IMMUNOGEN INC - Form 10-Q

In March 2016, the FASB issued Accounting Standards Update 2016-9, *Improvements to Employee Share-Based Payment Accounting (Topic 718)* that changes the accounting for certain aspects of share-based payments to employees. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid in capital pools. The guidance also allows for the employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis. The guidance is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods with early adoption permitted. Accordingly, the standard is effective for us on July 1, 2017. We are currently evaluating the impact of this guidance on our financial statements and the timing of adoption.

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, 2015. 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, 2015. Since then there have been no material changes to our market risks or to our management of such risks.

ITEM 4. *Controls and Procedures*

(a) *Disclosure Controls and Procedures*

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

(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 March 31, 2016 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. *Risk Factors*

You should carefully review and consider the information regarding certain factors that could materially affect our business, financial condition or future results set forth under Item 1A. (Risk Factors) in our Annual Report on Form 10-K for the fiscal year ended June 30, 2015. There have been no material changes from the factors disclosed in our 2015 Annual Report on Form 10-K, although we may disclose changes to such factors or disclose additional factors from time to time in our future filings with the Securities and Exchange Commission.

Table of Contents

ITEM 6. ***Exhibits***

Exhibit No.	Description
10.1	Amendment to Stock Option Agreements between the Registrant and Daniel M. Junius
31.1	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002
32	Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

Furnished, not filed.

Table of Contents

SIGNATURES

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

ImmunoGen, Inc.

Date: May 4, 2016

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

Date: May 4, 2016

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