February 03, 2016 **Table of Contents UNITED STATES** SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-Q (Mark One) (X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended December 31, 2015 or ( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period from \_\_\_\_\_ to \_\_\_\_ Commission File Number: 0-12104 Immunomedics, Inc. (Exact name of Registrant as specified in its charter)

**IMMUNOMEDICS INC** 

Form 10-O

Delaware 61-1009366

(State or other jurisdiction of (I.R.S. Employer Identification No.)

incorporation or organization)

300 The American Road, Morris Plains, New Jersey 07950

(Address of principal executive offices) (Zip Code)

(973) 605-8200

(Registrant's Telephone Number, Including Area Code)

Former Name, Former Address and Former Fiscal Year,

If Changed Since Last Report: Not Applicable

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 Web site, 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 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 definitions of "accelerated filer", "large accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Non-Accelerated Filer Smaller Reporting Company

Indicate by	check mark	whether t	the registrant	is a shell	company	(as defined	l in Rule	12b-2 of t	he Exchang	e
Act). Yes	No									

The number of shares of the registrant's common stock outstanding as of February 2, 2016 was 94,741,150.

## Table of Contents

IMMUNOMEDICS, INC.

## TABLE OF CONTENTS

PART I:	FINANCIAL INFORMATION	
ITEM 1.	FINANCIAL STATEMENTS:	
	Unaudited Condensed Consolidated Balance Sheets as of December 31, 2015 and June 30, 2015	1
	Unaudited Condensed Consolidated Statements of Comprehensive Loss for the Three and Six Months Ended December 31, 2015 and 2014	2
	Unaudited Condensed Consolidated Statements of Cash Flows for the Six Months Ended December 31, 2015 and 2014	3
	Notes to Unaudited Condensed Consolidated Financial Statements	4
ITEM 2.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	22
ITEM 3.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	37
<u>ITEM 4.</u>	CONTROLS AND PROCEDURES	38
PART II:	OTHER INFORMATION	
ITEM 1.	LEGAL PROCEEDINGS	39
<u>ITEM</u> 1A.	RISK FACTORS	40
<u>ITEM 6.</u>	<u>EXHIBITS</u>	58
SIGNAT	<u>URES</u>	59
<u>EXHIBIT</u>	<u>CINDEX</u>	60

## Table of Contents

## IMMUNOMEDICS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	December 31, 2015	June 30, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 13,716,207	\$ 13,452,775
Marketable securities	62,328,031	86,165,532
Accounts receivable, net of allowance for doubtful accounts of \$67,475 at		
December 31, 2015 and \$54,177 at June 30, 2015	409,225	345,627
Inventory	490,704	584,424
Other receivables	26,779	857,068
Prepaid expenses	1,490,654	1,136,103
Other current assets	315,079	945,673
Total current assets  Property and agginment, not of accumulated depreciation of \$28,227,002	78,776,679	103,487,202
Property and equipment, net of accumulated depreciation of \$28,227,002 and \$27,891,272 at December 31, 2015 and June 30, 2015, respectively	3,136,834	2,241,838
Other long-term assets	50,566	50,566
Total Assets	\$ 81,964,079	\$ 105,779,606
Total Assets	Ψ 01,704,077	Ψ 103,772,000
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 14,946,983	\$ 11,808,223
Deferred revenues	269,515	271,667
Total current liabilities	15,216,498	12,079,890
Convertible senior notes – net of unamortized debt issuance costs of		
\$3,010,512 at December 31, 2015 and \$3,375,423 at June 30, 2015	96,989,488	96,624,577
Other liabilities	1,649,518	1,599,760
Commitments and Contingencies		
Stockholders' Deficit:		
Preferred stock, \$.01 par value; authorized 10,000,000 shares; no shares		
issued and outstanding at December 31, 2015 and at June 30, 2015		
Common stock, \$.01 par value; authorized 155,000,000 shares; issued		
94,741,919 shares and outstanding 94,707,194 shares at December 31,		
2015; and issued 94,546,578 shares and outstanding 94,511,853 shares at	0.45 410	0.45.465
June 30, 2015	947,418	945,465
Capital contributed in excess of par	307,165,796	305,229,354
Treasury stock, at cost: 34,725 shares at December 31, 2015 and at June 30,	(450 270)	(450 270)
2015	(458,370)	(458,370)
Accumulated other comprehensive loss	(338,607,876) (277,630)	(309,468,004) (161,092)
Accumulated other comprehensive loss	(211,030)	(101,092)

Total Immunomedics, Inc. stockholders' deficit	(31,230,662)	(3,912,647)
Noncontrolling interest in subsidiary	(660,763)	(611,974)
Total stockholders' deficit	(31,891,425)	(4,524,621)
Total Liabilities and Stockholders' Deficit	\$ 81.964.079	\$ 105,779,606

See accompanying notes to unaudited condensed consolidated financial statements

## Table of Contents

IMMUNOMEDICS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF

### **COMPREHENSIVE LOSS**

(UNAUDITED)

	Three months ended December 31,		Six months ended December 31,	I
	2015	2014	2015	2014
Revenues:	2013	2014	2013	2014
Product sales	\$ 589,947	\$ 761,664	\$ 1,171,195	\$ 1,489,297
License fee and other revenues	25,403	<u> </u>	36,228	<u> </u>
Research and development	55,754	241,127	194,559	585,492
Total revenues	671,104	1,002,791	1,401,982	2,074,789
Costs and Expenses:				
Costs of goods sold	64,519	68,983	122,783	145,269
Research and development	14,261,676	10,364,850	27,174,806	19,756,867
Sales and marketing	386,696	174,795	530,217	403,432
General and administrative	1,655,841	1,856,036	3,380,135	5,675,228
Total costs and expenses	16,368,732	12,464,664	31,207,941	25,980,796
Operating loss	(15,697,628)	(11,461,873)	(29,805,959)	(23,906,007)
Interest expense	(1,369,956)		(2,739,911)	<del></del>
Interest and other income	83,762	11,216	175,720	36,288
Foreign currency transaction gain (loss),				
net	6,950	11,899	(3,511)	162
Loss before income tax benefit				
(expense)	(16,976,872)	(11,438,758)	(32,373,661)	(23,869,557)
Income tax benefit (expense)	3,204,250	(26,892)	3,185,000	(38,855)
Net loss	(13,772,622)	(11,465,650)	(29,188,661)	(23,908,412)
Less: Net loss attributable to				
noncontrolling interest	(26,572)	(30,415)	(48,789)	(62,757)
Net loss attributable to Immunomedics,				
Inc. stockholders	\$ (13,746,050)	\$ (11,435,235)	\$ (29,139,872)	\$ (23,845,655)
Loss per common share attributable to				
Immunomedics, Inc. stockholders (basic				
and diluted):	\$ (0.15)	\$ (0.12)	\$ (0.31)	\$ (0.26)
Weighted average shares used to				
calculate loss per common share (basic				
and diluted)	94,664,758	93,157,279	94,630,292	93,127,741
Other comprehensive loss, net of tax:				
Foreign currency translation adjustments	(54,739)	(79,703)	(37,271)	(257,833)
Unrealized loss on securities available				
for sale securities	(112,964)	(5,999)	(79,267)	(10,451)

Other comprehensive loss	(167,703)	(85,702)	(116,538)	(268,284)
Comprehensive loss	(13,940,325)	(11,551,352)	(29,305,199)	(24,176,696)
Less comprehensive loss attributable to				
noncontrolling interest	(26,572)	(30,415)	(48,789)	(62,757)
Comprehensive loss attributable to				
Immunomedics, Inc. stockholders	\$ (13,913,753)	\$ (11,520,937)	\$ (29,256,410)	\$ (24,113,939)

See accompanying notes to unaudited condensed consolidated financial statements

## Table of Contents

### IMMUNOMEDICS, INC. AND SUBSIDIARIES

### CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Six Months Ende December 31,	ed
	2015	2014
Cash flows from operating activities:		
Net loss	\$ (29,188,661)	\$ (23,908,412)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	336,127	281,634
Amortization of deferred revenue	(2,152)	(11,688)
Amortization of bond premiums	381,107	233,440
Amortization of debt issuance costs	364,911	_
Amortization of deferred rent	49,758	49,758
Gain from the sales of marketable securities	(1,844)	(9,898)
Increase (decrease) in allowance for doubtful accounts	13,298	(20,752)
Non-cash expense related to stock compensation	1,965,816	1,515,129
Changes in operating assets and liabilities	4,258,184	2,296,480
Net cash used in operating activities	(21,823,456)	(19,574,309)
Cash flows from investing activities:		
Purchases of marketable securities	(2,749,117)	(3,244,370)
Proceeds from sales/maturities of marketable securities	26,128,088	19,478,097
Purchases of property and equipment	(1,230,726)	(439,599)
Net cash provided by investing activities	22,148,245	15,794,128
Cash flows from financing activities:		
Exercise of stock options	158,079	80,959
Tax withholding payments for stock compensation	(185,499)	(221,291)
Net cash used in financing activities	(27,420)	(140,332)
Effect of changes in exchange rates on cash and cash equivalents	(33,937)	(192,291)
Net increase (decrease) in cash and cash equivalents	263,432	(4,112,804)
Cash and cash equivalents beginning of period	13,452,775	6,961,494
Cash and cash equivalents end of period	\$ 13,716,207	\$ 2,848,690
Supplemental disclosure of cash flow information:		
Interest paid	\$ 2,427,778	\$ —

See accompanying notes to unaudited condensed consolidated financial statements.

#### **Table of Contents**

IMMUNOMEDICS, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED

FINANCIAL STATEMENTS

Reference is made to the Annual Report on Form 10-K of Immunomedics, Inc., a Delaware corporation ("Immunomedics," the "Company," "we," "our" or "us"), for the fiscal year ended June 30, 2015, which contains our audited consolidated financial statements and the notes thereto.

#### 1. Business Overview and Basis of Presentation

Immunomedics is a clinical-stage biopharmaceutical company that develops monoclonal antibody-based products for the targeted treatment of cancer, autoimmune and other serious diseases. The Company has continued to transition its focus away from the development and commercialization of diagnostic imaging products in order to accelerate the development of its therapeutic product candidates, although the Company still manufactures and commercializes its LeukoScan® product in territories where regulatory approvals have previously been granted in Europe, Canada and in other markets outside the U.S. LeukoScan® is indicated for diagnostic imaging for determining the location and extent of infection and inflammation in bone of patients with suspected osteomyelitis, including patients with diabetic foot ulcers.

The Company has two foreign subsidiaries, Immunomedics B.V. in the Netherlands and Immunomedics GmbH in Rodermark, Germany, that assist the Company in managing sales efforts and coordinating clinical trials in Europe. In addition, included in the accompanying condensed financial statements is the majority-owned U.S. subsidiary, IBC Pharmaceuticals, Inc. ("IBC"), which works on the development of novel cancer radiotherapeutics using patented pre-targeting technologies with proprietary, bispecific antibodies.

The accompanying unaudited condensed consolidated financial statements of Immunomedics, which incorporate our subsidiaries, have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), for interim financial information and the instructions to the Quarterly Report on Form 10 Q and Regulation S X. Accordingly, the statements do not include all of the information and footnotes required by GAAP for complete annual financial statements. With respect to the financial information for the interim periods included in this Quarterly Report on Form 10-Q, which is unaudited, management believes that all adjustments (consisting of normal recurring accruals), considered necessary for a fair presentation of the results for such interim periods have been included. Operating results for the three and six-month periods ended December 31, 2015 are not necessarily indicative of the results that may be expected for the full fiscal year ending June 30, 2016, or any other period.

Immunomedics is subject to significant risks and uncertainties, including, without limitation, the risk that the Company may be unable to successfully obtain financing for product development; the Company's inability to further identify, develop and achieve commercial success for new products and technologies; the possibility of delays in the research and development necessary to select drug development candidates and delays in clinical trials; the risk that clinical trials may not result in marketable products; the risk that the Company or its' collaborators may be unable to secure regulatory approval of and market its drug candidates; the Company's dependence upon pharmaceutical and biotechnology collaborations; the levels and timing of payments under the Company's collaborative agreements, if any; uncertainties about the Company's ability to obtain new corporate collaborations and acquire new technologies on satisfactory terms, if at all; the development or regulatory approval of competing products; the Company's ability to protect its proprietary technologies; patent-infringement claims; and risks of new, changing and competitive

technologies and regulations in the United States and internationally.

### **Table of Contents**

Since its inception in 1982, Immunomedics' principal sources of funds have been the private and public sale of equity and debt securities and revenues from licensing agreements, which could provide up-front and milestone payments, as well as funding of development costs and other licensing terms.

As of December 31, 2015, the Company had cash, cash equivalents and marketable securities totaling \$76.0 million. The Company's budgeted cash requirements in fiscal year 2016 includes expenses related to the clivatuzumab tetraxetan Phase 3 clinical trial for the treatment of patients with pancreatic cancer, activities in preparing for the Phase 3 clinical trials for sacituzumab govitecan, as well as for expenses for the ongoing Phase 2 expansion ADC clinical trials (sacituzumab govitecan and labetuzumab govitecan). For the six-month period ended December 31, 2015 the Company utilized cash, cash equivalents and marketable securities aggregating \$21.8 million related to its operating activities. Based on the Company's cash flow projections, the Company believes it has sufficient funds to continue its operations and research and development programs for at least the next twelve months.

Future financial demands include ongoing operating expenses, Phase 3 and Phase 2 clinical trials, and further development of various clinical trial programs in fiscal 2017 and beyond. Until the Company can generate significant cash from its operations, the Company expects to continue to fund its operations with its available financial resources. These financial resources may not be adequate to sustain its operations and the Company will be required to finance future cash needs through strategic collaboration agreements, or the sale of additional equity or debt securities. However, the Company cannot be certain that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or its stockholders. The capital markets have experienced volatility in recent years, which has resulted in uncertainties with respect to availability of capital and hence the timing to meet an entity's liquidity needs. Having insufficient funds may require the Company to delay, scale-back or eliminate some or all of its programs or renegotiate less favorable terms than it would otherwise choose. Failure to obtain adequate financing also may adversely affect its ability to operate as a going concern.

The Company continues to pursue business development and licensing arrangements as a potential source of financing. These activities include any new parties who may be interested in the Company's clinical programs as well as any licenses to the Company's intellectual property estate. The Company's current partners, The Bayer Group ("Bayer") and UCB, S.A., State and Federal Grants, along with potential debt and equity financing may also be other sources of financing.

### 2. Summary of Significant Accounting Policies

These unaudited condensed consolidated interim financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended June 30, 2015. The Company adheres to the same accounting policies in preparation of its interim financial statements.

## Principles of Consolidation and Presentation

The condensed consolidated financial statements include the accounts of Immunomedics and its subsidiaries. Noncontrolling interests in consolidated subsidiaries in the condensed consolidated balance sheets represent minority stockholders' proportionate share of the equity (deficit) in such subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

### **Table of Contents**

#### **Financial Instruments**

The carrying amounts of cash and cash equivalents, other current assets and current liabilities approximate fair value due to the short-term maturity of these instruments. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

#### Marketable Securities

Immunomedics adopted Accounting Standards Codification No. 320, Accounting for Investments—Debt and Equity Securities, to account for investments in marketable securities. Under this accounting standard, securities for which there are no positive intent and ability to hold to maturity, the securities are classified as available-for-sale and are carried at fair value. Unrealized holding gains and losses, which are deemed to be temporary, on securities classified as available-for-sale are carried as a separate component of accumulated other comprehensive loss.

Marketable securities, all of which are available-for-sale, consists of corporate debt securities, U.S. bonds, U.S. sponsored agencies and municipal bonds. Corporate debt securities include Eurodollar issues of U.S. corporations, and U.S. dollar denominated issues of foreign corporations. Marketable securities are carried at fair value, with unrealized gains and losses, net of related income taxes, reported as accumulated other comprehensive loss, except for losses from impairments which are determined to be other-than-temporary. Realized gains and losses, and declines in value judged to be other-than-temporary on available-for-sale securities are included in the determination of net loss and are included in interest and other income (net), at which time the average cost basis of these securities are adjusted to fair value. Fair values are based on quoted market prices at the reporting date. Interest and dividends on available-for-sale securities are included in interest and other income (net).

#### Inventory

Inventory, which consists only of the finished product of LeukoScan®, is stated at the lower of cost (which approximates first-in, first-out) or market, and includes materials, labor and manufacturing overhead.

### Revenue Recognition

The Company has accounted for revenue arrangements that include multiple deliverables as a separate unit of accounting if both of the following criteria are met: a) the delivered item has value to the customer on a standalone basis, and b) if the right of return exists, delivery of the undelivered items is considered probable and substantially in the control of the vendor. If these criteria are not met, the revenue elements must be considered a single unit of accounting for purposes of revenue recognition. The Company allocates revenue consideration, excluding contingent consideration, based on the relative selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables. Relative selling prices are determined using vendor specific objective evidence, if it exists; otherwise third-party evidence or the Company's best estimate of selling price is used for each deliverable.

Payments received under contracts to fund certain research activities are recognized as revenue in the period in which the research activities are performed. Payments received in advance that are related to future performance are deferred and recognized as revenue when the research projects are performed. Upfront nonrefundable fees associated with license and development agreements where the Company has continuing involvement in the agreement are recorded as deferred revenue and recognized over the estimated service period. The Company estimates the period of continuing involvement based on the best evidential matter

### **Table of Contents**

available at each reporting period. If the estimated service period is subsequently modified, the period over which the upfront fee is recognized is modified accordingly on a prospective basis.

In order to determine the revenue recognition for contingent milestones, the Company evaluates the contingent milestones using the criteria as provided by the Financial Accounting Standards Boards ("FASB") guidance on the milestone method of revenue recognition, as explained in ASU 2010-17, "Milestone Method of Revenue Recognition," at the inception of a collaboration agreement. The criteria requires that (i) the Company determines if the milestone is commensurate with either its performance to achieve the milestone or the enhancement of value resulting from the Company's activities to achieve the milestone, (ii) the milestone be related to past performance, and (iii) the milestone be reasonable relative to all deliverable and payment terms of the collaboration arrangement. If these criteria are met then the contingent milestones can be considered as substantive milestones and will be recognized as revenue in the period that the milestone is achieved. Royalties are recognized as earned in accordance with the terms of various research and collaboration agreements.

Revenue from the sale of diagnostic products is recorded when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable or collectability is reasonably assured. Allowances, if any, are established for uncollectible amounts, estimated product returns and discounts. Since allowances are recorded based on management's estimates, actual amounts may be different in the future.

### Research and Development Costs

Research and development costs are expensed as incurred. Costs incurred for clinical trials for patients and investigators are expensed as services are performed in accordance with the agreements in place with their clinical sites.

#### Reimbursement of Research & Development Costs

Research and development costs that are reimbursable under collaboration agreements are included as a reduction of research and development expenses. The Company records these reimbursements as a reduction of research and development expenses as the Company's partner in the collaboration agreement has the financial risks and responsibility for conducting these research and development activities.

#### **Stock-Based Compensation**

The Company utilizes stock-based compensation in the form of stock options, stock appreciation rights, stock awards, stock unit awards, performance shares, cash-based performance units and other stock-based awards, each of which may be granted separately or in tandem with other awards.

The grant-date fair value of stock awards is based upon the underlying price of the stock on the date of grant. The grant-date fair value of stock option awards must be determined using an option pricing model. Option pricing models require the use of estimates and assumptions as to (a) the expected term of the option, (b) the expected volatility of the price of the underlying stock and (c) the risk-free interest rate for the expected term of the option. The Company uses the Black-Scholes-Merton option pricing formula for determining the grant-date fair value of such awards.

The expected term of the option is based upon the contractual term and expected employee exercise and expected post-vesting employment termination behavior. The expected volatility of the price of the underlying stock is based upon the historical volatility of the Company's stock computed over a period of

#### **Table of Contents**

time equal to the expected term of the option. The risk free interest rate is based upon the implied yields currently available from the U.S. Treasury yield curve in effect at the time of the grant. Pre-vesting forfeiture rates are estimated based upon past voluntary termination behavior and past option forfeitures.

The following table sets forth the weighted-average assumptions used to calculate the fair value of options granted for the six-month periods ended December 31, 2015 and 2014:

	Six Months Ended December 31,		
	2015	2014	
Expected dividend yield	0%	0%	
Expected option term (years)	5.03	5.07	
Expected stock price volatility	56%	59%	
Risk-free interest rate	1.28% - 1.64%	1.60% - 1.62%	

The Company uses historical data to estimate forfeitures. The expected term of options granted represents the period of time that options granted are expected to be outstanding. Expected stock price volatility was calculated based on the Company's daily stock trading history. The risk-free rate for periods within the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

Changes in any of these assumptions could impact, potentially materially, the amount of expense recorded in future periods related to stock-based awards.

#### **Income Taxes**

The Company uses the asset and liability method to account for income taxes, including the recognition of deferred tax assets and deferred tax liabilities for the anticipated future tax consequences attributable to differences between financial statement amounts and their respective tax bases. The Company reviews its deferred tax assets for recovery. A valuation allowance is established when the Company believes that it is more likely than not that its deferred tax assets will not be realized. Changes in valuation allowances from period to period are included in the Company's tax provision in the period of change. The Company has recorded a full valuation allowance against its net deferred tax assets as of December 31, 2015.

At June 30, 2015, the Company has available net operating loss carry forwards for federal income tax reporting purposes of approximately \$231.0 million and for state income tax reporting purposes of approximately \$103.4 million, which expire at various dates between fiscal 2016 and 2035. Available net operating loss carryforwards for state income tax reporting purposes were reduced in December 2015, resulting from the sale of net operating loss as described below. Pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, the annual utilization of a company's net operating loss and research credit carry forwards may be limited if the Company experiences a change in ownership as defined in Section 382 of the Internal Revenue Code. The Company's net operating loss carry forwards available to offset future federal taxable income arising before such ownership changes may be limited. Similarly, the Company may be restricted in using its research credit carry forwards arising before such ownership changes to offset future federal income tax expense.

The majority-owned subsidiary of the Company (IBC Pharmaceuticals, Inc.) is currently under examination by the Internal Revenue Service for the fiscal year ended December 31, 2013.

The Company's U.S. operations reported a net loss for the three and six-month periods ended December 31, 2015, resulting in a tax benefit that was fully offset by a valuation allowance. Income taxes previously provided for profitable foreign jurisdictions during the first three months of fiscal 2016 were

#### **Table of Contents**

reversed as a result of the net loss for the six-month period ended December 31, 2015 with respect to such jurisdictions. The Company's U.S. operations reported a net loss for the three and six-month periods ended December 31, 2014, resulting in a tax benefit that was fully offset by a valuation allowance. Income taxes were provided for profitable foreign jurisdictions at the estimated annual tax rate during the three and six-month periods ended December 31, 2014.

The Company sold certain State of New Jersey State Net Operating Losses ("NOL") and Research and Development ("R&D") tax credits through the New Jersey Economic Development Authority Technology Business Tax Certificate Transfer Program. Pursuant to such sale, during the three and six-month periods ended December 31, 2015, the Company recorded a tax benefit of \$3.2 million as a result of its sale of approximately \$35.9 million of New Jersey State NOL and \$1.3 million of New Jersey R&D tax credits.

The Company has no liability for uncertain tax positions as of December 31, 2015.

Net Loss Per Share Allocable to Common Stockholders

Net loss per basic and diluted common share allocable to common stockholders is based on the net loss for the relevant period, divided by the weighted-average number of common shares outstanding during the period. For purposes of the diluted net loss per common share calculations, the exercise or conversion of all potential common shares is not included because their effect would have been anti-dilutive, due to the net loss recorded for the three and six-month periods ended December 31, 2015 and 2014. The common stock equivalents excluded from the diluted per share calculation are 27,902,219 and 7,488,710 shares at December 31, 2015 and 2014, respectively.

### Net Comprehensive Loss

Net comprehensive loss consists of net loss, unrealized loss on available for sale securities and foreign exchange translation adjustments and is presented in the condensed consolidated statements of comprehensive loss.

### **Recently Issued Accounting Pronouncements**

In August 2014, the FASB issued ASU 2014-15, "Presentation of Financial Statements – Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". This guidance clarifies that an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The amendments in this update are effective for annual reporting periods ending after December 15, 2016, and annual and interim periods thereafter, and early application is permitted. The Company is assessing ASU 2014-15's impact and will adopt it when effective.

On May 28, 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers," which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In August 2015, with the issuance of ASU 2015-14, the FASB amended the effective date of this ASU to fiscal years beginning after December 15, 2017, and early adoption is permitted only for fiscal years beginning after December 15, 2016. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is assessing ASU 2014-09's impact and will adopt it when effective.

### Table of Contents

### 3. Marketable Securities

Marketable securities at December 31, 2015 consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Fair Value
U.S. Treasury Bonds	\$ 9,751	\$ —	\$ (12)	\$ 9,739
Certificate of Deposits	8,000		(3)	7,997
U.S. Government Sponsored Agencies	25,868	12	(24)	25,856
Corporate Debt Securities	18,777		(41)	18,736
	\$ 62,396	\$ 12	\$ (80)	\$ 62,328

Maturities of debt securities classified as available-for-sale were as follows at December 31, 2015 (in thousands):

		Net Carrying
	Fair Value	Amount
Due within one year	\$ 49,511	\$ 49,695
Due after one year through five years	12,817	12,865
	\$ 62,328	\$ 62,560

Marketable securities at June 30, 2015 consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Fair Value
U.S. Treasury Bonds	\$ 13,375	\$ 14	\$ —	\$ 13,389
Certificate of Deposits	6,000	4	_	6,004
U.S. Government Sponsored Agencies	40,694	30	(9)	40,715
Corporate Debt Securities	26,085	2	(29)	26,058
-	\$ 86,154	\$ 50	\$ (38)	\$ 86,166

Maturities of debt securities classified as available-for-sale were as follows at June 30, 2015 (in thousands):

		Net Carrying
	Fair Value	Amount
Due within one year	\$ 46,516	\$ 46,646
Due after one year through five years	39,650	39,831
, ,	\$ 86,166	\$ 86,477

### 4. Convertible Senior Notes

In February 2015, the Company issued \$100.0 million of Convertible Senior Notes (net proceeds of \$96.3 million after deducting the initial purchasers' fees and offering expenses) in a private offering exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance upon Rule 144A under the Securities Act. The Convertible Senior Notes will mature on February 15, 2020, unless earlier purchased or converted. The debt issuance costs of approximately \$3.7 million, primarily consisting of underwriting, legal and other professional fees, are amortized over the term of the Convertible Senior Notes. The Convertible Senior Notes are senior unsecured obligations of the Company. Interest at 4.75% is payable

### **Table of Contents**

semiannually on February 15 and August 15 of each year. The effective interest rate on the Convertible Senior Note was 5.48% for the period from the date of issuance through December 31, 2015.

The Convertible Senior Notes are convertible at the option of holders into approximately 19.6 million shares of Immunomedics common stock at any time prior to the close of business on the day immediately preceding the maturity date. The conversion rate will initially be 195.8336 shares of common stock per \$1,000 principal amount of Convertible Senior Notes (equivalent to an initial conversion price of approximately \$5.11 per share of Immunomedics common stock).

If the Company undergoes a fundamental change (as defined in the indenture governing the Convertible Senior Notes), holders may require Immunomedics to purchase for cash all or part of the Convertible Senior Notes at a purchase price equal to 100% of the principal amount of the Convertible Senior Notes to be purchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change purchase date, subject to certain exceptions. In addition, if certain make-whole fundamental changes (as defined in the indenture governing the Convertible Senior Notes) occur, Immunomedics will, in certain circumstances, increase the conversion rate for any Convertible Note converted in connection with such make-whole fundamental change.

The indenture does not limit the amount of debt which may be issued by the Company under the indenture or otherwise, does not contain any financial covenants or restrict the Company from paying dividends, selling or disposing of assets, or issuing or repurchasing its other securities, provided that such event is not deemed to be a fundamental change (as defined in the indenture governing the Convertible Senior Notes). The indenture contains customary terms and covenants and events of default.

If an event of default with respect to the Convertible Senior Notes occurs, holders may, upon satisfaction of certain conditions, accelerate the principal amount of the Convertible Senior Notes plus premium, if any, and accrued and unpaid interest, if any. In addition, the principal amount of the Convertible Senior Notes plus premium, if any, and accrued and unpaid interest, if any, will automatically become due and payable in the case of certain types of bankruptcy or insolvency events of default involving the Company.

Total interest expense for the Convertible Senior Notes was \$1.4 million and \$2.7 million for the three and six-month periods ended December 31, 2015, respectively, including amortization of debt issuance costs of \$0.2 million and \$0.4 million, respectively.

#### 5. Estimated Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, accounts receivable, accounts payable and accrued expenses, and Convertible Senior Notes. The carrying amount of accounts receivable, accounts payable and accrued expenses are generally considered to be representative of their respective fair values because of the short-term nature of those instruments as of December 31, 2015 and June 30, 2015.

The Company has categorized its other financial instruments, based on the priority of the inputs to the valuation technique, into a three-level fair value hierarchy as set forth below. If the inputs used to measure the financial instruments fall within different levels of the hierarchy, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

### **Table of Contents**

Financial instruments recorded on the condensed consolidated balance sheets as of December 31, 2015 and June 30, 2015 are categorized based on the inputs to the valuation techniques as follows (in thousands):

- · Level 1 Financial instruments whose values are based on unadjusted quoted prices for identical assets or liabilities in an active market which the company has the ability to access at the measurement date (examples include active exchange-traded equity securities and most U.S. Government and agency securities).
- · Level 2 Financial instruments whose value are based on quoted market prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets.
- · Level 3 Financial instruments whose values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs reflect management's own assumptions about the assumptions a market participant would use in pricing the asset.

Cash equivalents and marketable securities:

(\$ in thousands)			
	Level	Level	
Level 1	2	3	Total
\$ 7,644	\$ —	\$ —	\$ 7,644
9,739	_		9,739
7,997	_		7,997
25,856			25,856
18,736			18,736
\$ 69,972	\$ —	\$ —	\$ 69,972
	Level 1 \$ 7,644 9,739 7,997 25,856 18,736	Level 1 2 \$ 7,644 \$ —  9,739 — 7,997 — 25,856 — 18,736 —	Level Level  Level 1 2 3 \$ 7,644 \$ — \$ —  9,739 — —  7,997 — —  25,856 — —  18,736 — —

	(\$ in thousands)			
		Level	Level	
June 30, 2015	Level 1	2	3	Total
Money Market Funds	\$ 10,138	\$ —	\$ —	\$ 10,138
Marketable Securities:				
U.S. Treasury Bonds	13,389	_	_	13,389
Certificate of Deposits	6,004	_	_	6,004
U.S. Government Sponsored Agencies	40,715	_		40,715
Corporate Debt Securities	26,058	_		26,058
Total	\$ 96,304	\$ —	\$ —	\$ 96,304

The money market funds noted above are included in cash and cash equivalents.

### **Table of Contents**

#### Convertible Senior Notes

The carrying amounts and estimated fair values (Level 2) of debt instruments are as follows (in thousands):

	As of December	31, 2015	As of June	30, 2015
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Convertible Senior Notes	\$ 96,989	\$ 86,511	\$ 96,625	\$ 103,800

The fair value of the Convertible Senior Notes, which differs from their carrying values, is influenced by interest rates, the Company's stock price and stock price volatility and is determined by prices for the Convertible Senior Notes observed in market trading which are Level 2 inputs.

### 6.Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss were as follows (in thousands):

cy Gains (Losses) on	Accumulated Other
(Losses) on	
(Losses) on	
tion Available-	Comprehensive
nents for-Sale Securities	Loss
3) \$ 12	\$ (161)
(78)	(115)
(2)	(2)
(80)	(117)
(68)	(278)
<del></del>	262
<del></del>	(258)
(10)	(10)
(10)	(268)
\$ (10)	\$ (6)
)	for-Sale Securities  3) \$ 12 (78)  (2) (80) (68) — (3) — (10) (10)

<sup>(</sup>a) For the six-month periods ended December 31, 2015 and 2014, \$2 thousand and \$10 thousand was reclassified from accumulated other comprehensive loss to interest and other income, respectively.

All components of accumulated other comprehensive loss are net of tax, except currency translation adjustments, which exclude income taxes related to indefinite investments in foreign subsidiaries.

### 7.Stock Incentive Plan

The Company has a stock incentive plan, the Immunomedics, Inc. 2014 Long-Term Incentive Plan (the "Plan"), that includes a discretionary grant program, a stock issuance program and an automatic grant program. The plan was established to promote the interests of the Company, by providing eligible persons with the opportunity to acquire a proprietary interest in the Company as an incentive to remain with the organization and to align the employee's interest with our stockholders.

### **Table of Contents**

Under the Plan option awards are generally granted with an exercise price equal to the closing price of the Company's common stock on the date of grant. Those option awards generally vest based on four years of continuous service and have seven year contractual terms. Option awards that are granted to non-employee Board members under the annual option grant program are granted with an exercise price equal to the closing price of the Company's common stock on the date of grant, are vested immediately and have seven year contractual terms. At December 31, 2015, there were 17,067,955 shares of common stock reserved for possible future issuance under the Plan, both currently outstanding (7,318,859 shares) and those available to be issued for future grants (9,749,096 shares).

The weighted average fair value at the date of grant for options granted during the six-month periods ended December 31, 2015 and 2014 were \$1.00 and \$1.80 per share, respectively. The Company uses historical data to estimate employee forfeitures for employees, executive officers and outside directors. The expected term of options granted represents the period of time that options granted are expected to be outstanding and the expected stock price volatility is based on the Company's daily stock trading history. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

Information concerning options for the six-month period ended December 31, 2015 is summarized as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value (in 000's)
Outstanding, July 1, 2015	4,525,340	\$ 3.48		
Granted	601,431	\$ 2.04		
Exercised	(88,250)	\$ 2.24		
Cancelled or forfeited	(3,500)	\$ 4.09		
Outstanding, December 31, 2015	5,035,021	\$ 3.33	3.58	\$ 1,212
Exercisable, December 31, 2015	3,475,370	\$ 3.32	2.57	\$ 611

A summary of the Company's non-vested restricted and performance stock units at December 31, 2015, and changes during the six-month period ended December 31, 2015 are presented below:

Outstanding Non-Vested		Weighted-Average per Share of Market Value on		
Restricted and Performance Stock Units	Number of Awards	Gra	ınt Date	
Non-vested at July 1, 2015	706,881	\$	4.30	
Restricted Units Granted(a)	272,081	\$	2.05	
Restricted Units Granted – vesting based on certain market				
conditions(b)	1,500,000	\$	2.28	(c)
Vested/Exercised	(195,124)	\$	3.88	
Non-vested at December 31, 2015	2,283,838	\$	2.74	

For the six-month period ended December 31, 2015, 198,864 restricted stock units were awarded to the Company's President and Chief Executive Officer and 15,341 restricted stock units were awarded to the Company's Chief Financial Officer.

#### **Table of Contents**

- (b) For the six-month period ended December 31, 2015, 1,500,000 restricted stock units were awarded to the Company's Chairman, Chief Scientific Officer and Chief Patent Officer.
- (c) Represents fair value on date of grant determined by using Monte Carlo simulation technique.

The Company has 3,843,489 non-vested options, restricted stock units and performance stock units outstanding as of December 31, 2015. As of December 31, 2015, there was \$7.1 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is being recognized over a weighted-average period of 2.5 years. The Company recorded \$1.1 million and \$2.0 million for total stock-based compensation expense for employees, executive officers and non-employee Board members for the three and six-month periods ended December 31, 2015, respectively as compared to \$0.9 million and \$1.5 million for the three and six-month periods ended December 31, 2014, respectively.

Each non-employee Board member who continues to serve on the Board shall receive on the date of the annual stockholders meeting a grant of non-qualified stock options and restricted stock units, each equal in value to \$45 thousand. The Company recognizes the related stock-based compensation expense ratably over the fiscal year. In total, the Company recorded \$46 thousand and \$91 thousand for stock-based compensation expense for these non-employee Board members restricted stock units for each of the three and six-month periods ended December 31, 2015 and 2014, respectively. Stock-based compensation expense regarding non-qualified stock options for these non-employee Board members become vested and are expensed when issued, during the second quarter of each fiscal year.

On August 20, 2015, the Company awarded an additional 214,205 restricted stock units to certain executive officers of the Company at the closing price on that date (\$1.76 per share). These restricted stock units will vest over a four year period. As of December 31, 2015, there was \$1.2 million of total unrecognized compensation costs related to non-vested share-based compensation arrangements granted under the Plan for these executive officers, excluding performance stock units. The cost is being recognized over a weighted-average period of 2.5 years. The Company recorded \$0.2 million and \$0.3 million for stock-based compensation expense for restricted stock units for the three and six-month periods ended December 31, 2015, respectively, and \$0.2 million and \$0.4 million for the three and six-month periods ended December 31, 2014, respectively.

As part of the Amended and Restated Employment Agreement with Dr. Goldenberg which became effective July 1, 2015, (see Note 11), Dr. Goldenberg received a grant of 1,500,000 Restricted Stock Units, which shall vest, if at all, after the three (3) year period commencing on the grant date of July 14, 2015, provided the applicable milestones based on achievement of certain market conditions (stock prices) are met and conditioned upon Dr. Goldenberg's continued employment through the vesting period, subject to the terms and conditions of the Restricted Stock Units Notice and the Restricted Stock Units Agreement and such other terms and conditions as set forth in the grant agreement. The Company recorded \$0.3 million and \$0.5 million for the stock-based compensation for the three and six-month periods ended December 31, 2015 for this agreement. There is \$2.9 million of total unrecognized compensation cost related to these non-vested Restricted Stock Units granted as of December 31, 2015. That cost is being recognized over a remaining weighted-average period of 2.5 years.

During fiscal year 2014 the Company awarded certain executive officers Performance Units (as such term is defined in the Plan) of up to 389,864 units of restricted stock units which are subject to attainment of certain performance milestones as well as certain continued service requirements. All or a portion of the Performance Units vest based upon the level of achievement of the milestones set forth in each agreement,

#### **Table of Contents**

which is expected to be achieved within five years of the grant date. The Performance Units that vest based upon attainment of the performance milestone will be exercisable based on a percentage basis on the attainment of anniversary dates. During the six-month period ended December 31, 2015, the Company awarded 19,493 of these restricted stock units to the executive officers as a result of achieving one of the performance milestones. In fiscal year 2015, 116,959 units were awarded from achieving two performance milestones. As of December 31, 2015, one performance milestone has not been achieved and there are 253,412 Performance Units available if all performances are achieved within five years of grant date. The Company recorded \$0.1 million and \$0.2 million for the stock-based compensation for the three and six-month periods ended December 31, 2015, as compared to \$0.2 million for the stock-based compensation for the three and six-month periods ended December 31, 2014, respectively. There is \$0.3 million of total unrecognized compensation cost related to these non-vested Performance Units granted as of December 31, 2015. That cost is being recognized over a weighted-average period of 2.1 years. The unrecognized compensation cost is subject to modification on a quarterly basis based on review of performance probability and requisite achievement periods.

### 8. Geographic Segments

Immunomedics manages its operations as one line of business of researching, developing, manufacturing and marketing biopharmaceutical products, particularly antibody-based products for cancer, autoimmune and other serious diseases, and it currently reports as a single industry segment. Immunomedics conducts its research and development activities primarily in the United States. Immunomedics markets and sells LeukoScan® throughout Europe and in certain other countries outside the United States.

The following table presents financial information based on the geographic location of the facilities of Immunomedics as of and for the three and six-months ended December 31, 2015 and 2014 (\$ in thousands):

	As of and for the three months ended		
	December 31, 2015		
	United		
	States	Europe	Total
Total assets	\$ 80,833	\$ 1,131	\$ 81,964
Property and equipment, net	3,109	28	3,137
Revenues	81	590	671
Loss before income tax benefit	(16,761)	(216)	(16,977)

	As of and for the three months ended December 31, 2014		
	United		
	States	Europe	Total
Total assets	\$ 24,573	\$ 2,214	\$ 26,787
Property and equipment, net	2,053		2,053
Revenues	241	762	1,003

(Loss) income before income tax expenses (11,517) 78 (11,439)

#### **Table of Contents**

Six Months Ended
December 31, 2015
United
States Europe Total
Total revenues \$ 231 \$ 1,171 \$ 1,402
Loss before income tax benefit (32,188) (186) (32,374)

Six Months Ended
December 31, 2014
United
States Europe Total
Total revenues \$ 610 \$ 1,465 \$ 2,075
(Loss) income before tax expenses (23,972) 102 (23,870)

### 9. Related Party Transactions

Certain of the Company's affiliates, including members of its senior management and Board of Directors, as well as their respective family members and other affiliates, have relationships and agreements among themselves as well as with the Company and its affiliates, that create the potential for both real, as well as perceived, conflicts of interest. These include Dr. David M. Goldenberg, the Company's Chairman, Chief Scientific Officer and Chief Patent Officer, Ms. Cynthia L. Sullivan, the President and Chief Executive Officer, who is the wife of Dr. David M. Goldenberg, and certain companies with which the Company does business, including the Center for Molecular Medicine and Immunology ("CMMI"), which is currently in the process of dissolving, and IBC Pharmaceuticals, Inc.

The Company incurred \$5 thousand and \$14 thousand of legal expenses on behalf of CMMI for patent related matters for the three and six-month periods ended December 31, 2015, as compared to \$12 thousand and \$22 thousand for the three and six-month periods ended December 31, 2014, respectively. The Company has first rights to license those patents, and may decide whether or not to support them. However, any inventions made independently of the Company by CMMI are the property of CMMI.

For the three and six-month periods ended December 31, 2015, Dr. Goldenberg received approximately \$22 thousand and \$44 thousand, respectively, in compensation for his services to IBC. For the three and six-month periods ended December 31, 2014, such compensation was approximately \$21 thousand and \$42 thousand, respectively.

### 10.License and Collaboration Agreements

The Bayer Group (formerly Algeta ASA)

In fiscal year 2013 the Company entered into a collaboration agreement, referred to herein as the Collaboration Agreement, with Algeta ASA (subsequently acquired by The Bayer Group "Bayer"), for the development of epratuzumab to be conjugated with Algeta's proprietary thorium-227 alpha-pharmaceutical payload. Under the terms of the Collaboration Agreement, the Company manufactured and supplied clinical-grade epratuzumab to Bayer, which has rights to evaluate the potential of a Targeted Thorium Conjugate (TTC), linking thorium-227 to epratuzumab, for the treatment of patients with cancer. Bayer has the right to terminate the Collaboration Agreement with three months prior written notice, subject to certain provisions. Bayer will

### **Table of Contents**

fund all non-clinical and clinical development costs up to the end of Phase 1 clinical testing. Upon successful completion of Phase 1 testing, the parties shall negotiate terms for a license agreement at Bayer's request. The Company and Bayer have agreed to certain parameters in the Collaboration Agreement. Under the terms of the Collaboration Agreement, as amended, Immunomedics received an upfront cash payment and other payments aggregating \$6.0 million, which have been recognized in prior periods upon the Company fulfilling its obligations under the Collaboration Agreement.

For the year ended June 30, 2015, the Company recognized \$1.0 million in license and other revenue for the completion of the clinical development milestone as described in the Collaboration Agreement, which required the shipment of sufficient quantities of clinical grade material to Bayer to complete their Phase 1 clinical trial. In addition, in January 2015, the Company recorded revenue of \$0.3 million representing an anniversary payment under the agreement. The contract provides for the Company to receive two similar payments of \$0.3 million each, representing "anniversary payment" over the next two years.

### UCB, S.A.

On May 9, 2006, the Company entered into an agreement with UCB, S.A. referred to herein as UCB, providing UCB an exclusive worldwide license to develop, manufacture, market and sell epratuzumab for the treatment of all non-cancer indications referred to herein as the UCB Agreement. On December 27, 2011, the Company entered into the Amendment Agreement with UCB which provided UCB the right to sublicense epratuzumab, subject to obtaining the Company's prior consent, to a third party for the United States and certain other territories.

The Company also issued to UCB on December 27, 2011 a 5-year warrant to purchase one million shares of the Company's common stock, par value \$0.01 per share, at an exercise price of \$8.00 per share. In exchange for the right to sublicense its rights in epratuzumab to a third party and the warrant issuance, the Company received a non-refundable cash payment of \$30.0 million in January 2012. Further, under the terms of the Amendment Agreement, UCB surrendered its buy-in right with respect to epratuzumab in the field of oncology, which had been granted under the UCB Agreement. As of December 31, 2015, UCB has not executed a sublicense agreement with a third-party.

Collectively, pursuant to the UCB Agreement and the Amendment Agreement the Company is entitled to receive (i) up to \$130.0 million in cash payments and \$20.0 million in equity investments in regulatory milestone payments and (ii) up to \$260.0 million related to the achievement of specified product sales milestones. The Company is also entitled to product royalties ranging from a mid-teen to mid-twenty percentage of aggregate annual net sales under the UCB Agreement and Amendment Agreement during the product royalty term, (subject to reduction in certain circumstances). No development milestone, commercialization milestone or royalty payments were achieved through December 31, 2015. There can be no assurance that the development or commercialization milestones or royalty payment thresholds under the UCB Agreement and Amendment Agreement will be met and therefore there can be no assurance that the Company will receive such future payments.

On July 28, 2015, UCB announced that the two Phase 3 EMBODY<sup>TM</sup> clinical trials for epratuzumab in SLE did not meet the primary clinical efficacy endpoints in either dose in both studies. UCB is in the process of analyzing the full set of data from both studies. The UCB Agreement is still in effect. At this time it is unclear if any milestones will be achieved.

The UCB Agreement shall terminate in accordance with the terms thereof, by mutual written consent. In the event UCB decides to cease all development and commercialization of epratuzumab pursuant to the Agreement, UCB must promptly notify the Company, and the UCB Agreement will be deemed expired 30

#### **Table of Contents**

days following receipt of notice. Either the Company or UCB has the right to terminate the UCB Agreement by notice in writing to the other party upon or after any material breach of the UCB Agreement by the other party, if the other party has not cured the breach within 60 days after written notice to cure has been given, with certain exceptions. Upon termination of the UCB Agreement, among other things, all rights and licenses granted by the Company to UCB shall terminate, all rights of UCB under the Immunomedics Patent Rights (as defined in the UCB Agreement) and Immunomedics Know-How (as defined in the UCB Agreement) shall revert to the Company, and UCB shall cease all use of the Immunomedics Patent Rights and Immunomedics Know-How. Further, all regulatory filings and Approvals (as defined in the UCB Agreement) and any other documents relating to or necessary to further develop and commercialize the Licensed Compound (as defined in the UCB Agreement) and Licensed Products (as defined in the UCB Agreement), including, without limitation, all sublicenses granted by UCB, and all of UCB's right, title and interest therein and thereto, shall be assigned to the Company at the Company's option. No additional amounts shall be payable on events occurring after the effective date of termination.

### 11. Commitments and Contingencies

### **Employment Contracts**

Effective July 1, 2015, the Company entered into the Amended and Restated Employment Agreement with Dr. Goldenberg pertaining to Dr. Goldenberg's service to the Company as the Company's Chairman of the Board, Chief Scientific Officer and Chief Patent Officer.

The Amended and Restated Goldenberg Agreement will continue, unless earlier terminated by the parties, until July 1, 2020. Dr. Goldenberg's current annual base salary under the Amended and Restated Goldenberg Agreement is \$0.6 million, which shall be reviewed annually for appropriate increases by the Board or the Compensation Committee. Dr. Goldenberg is also eligible to participate in the Company's incentive compensation plan in place for its senior level executives. Dr. Goldenberg's annual bonus target is 50% of his base salary, subject to achievement of performance goals established by the Compensation Committee, with a potential payout from 0 to 150% of the target amount. For the 2015 fiscal year the strategic goal to out-license sacituzumab govitecan was not met. Taking into account the importance to the Company of out-licensing sacituzumab govitecan, the Compensation Committee determined that although certain individual performance goals were met, the Company's overall strategic plan had not been accomplished and, therefore, any 2015 cash incentive to be paid to the named executive officers would be deferred until such time as this performance goal of out-licensing is met during fiscal 2016. At such time, the Compensation Committee will review the incentive payments to be paid at an amount to be determined by the Compensation Committee. Dr. Goldenberg will also be eligible to receive equity compensation awards under the Plan, or any such successor equity compensation plan as may be in place from time to time, at the discretion of the Compensation Committee.

In lieu of any annual performance equity or equity-based grants throughout the term of the Amended and Restated Goldenberg Agreement, Dr. Goldenberg received a grant of 1,500,000 Restricted Stock Units (as such term is defined in the Plan), which shall vest, if at all, after the three 3 year period commencing on the grant date of July 14, 2015, provided the applicable milestones based on achievement of certain market conditions (stock prices) are met and conditioned upon Dr. Goldenberg's continued employment through the vesting period, subject to the terms and conditions of the Restricted Stock Units Notice and the Restricted Stock Units Agreement and such other terms and conditions as set forth in the grant agreement.

#### **Table of Contents**

#### Cynthia L. Sullivan

Effective July 1, 2014, the Company entered into the Fifth Amended and Restated Employment Agreement with Cynthia L. Sullivan pertaining to Ms. Sullivan's service to the Company as the Company's President and Chief Executive Officer (the "Amended Sullivan Agreement"), which terminates on June 30, 2017. Ms. Sullivan's current annual base salary under the Amended Sullivan Agreement is \$0.6 million, which is reviewed annually for appropriate increases by the Board or the Compensation Committee. Ms. Sullivan's annual bonus target is 50% of her base salary, subject to achievement of performance goals, with a potential payout from 0% to 150% of the target amount. For the 2015 fiscal year the strategic goal to out-license sacituzumab govitecan was not met. Taking into account the importance to the Company of out-licensing sacituzumab govitecan, the Compensation Committee determined that although certain individual performance goals were met, the Company's overall strategic plan had not been accomplished and, therefore, any 2015 cash incentive to be paid to the named executive officers would be deferred until such time as this performance goal of out-licensing is met during fiscal 2016. At such time, the Compensation Committee will review the incentive payments to be paid at an amount to be determined by the Compensation Committee. Ms. Sullivan is also eligible to receive equity compensation awards under the Plan, or any such successor equity compensation plan as may be in place from time to time.

# Legal Matters

The following is a summary of legal matters that are outstanding:

### Shareholder complaints:

In fiscal year 2014, two separate shareholder derivative complaints were filed against the Company. First, on March 24, 2014, a complaint styled Kops v. Goldenberg, et al., was filed in the Superior Court of New Jersey, Chancery Division, General Equity Part, Morris County. Second, on April 18, 2014, a complaint styled Breitman v. Sullivan, et al., was filed in the United States District Court for the District of New Jersey. The complaints alleged, among other things, that the Company and certain directors and officers breached their fiduciary duties for disseminating false and misleading information relating to the termination of the License and Collaboration Agreement that the Company entered into with Nycomed GmbH ("Nycomed") which provided Nycomed a worldwide license to develop, manufacture and commercialize veltuzumab, in the subcutaneous formulation, for the treatment of all non-cancer indications (the "Nycomed Agreement"). In particular, the complaints alleged that defendants failed to make timely disclosure concerning a dispute concerning a delay in the development of veltuzumab. On October 9, 2013, the Company announced that the Nycomed Agreement was terminated. The complaints alleged that the breaches in fiduciary duties by the directors and officers caused damages to the Company and stockholders, including a decline in value of the Company's common stock, increased investigatory and litigation costs, and exposure to civil liability as a result of a pending securities fraud class action suit. Plaintiffs brought the derivative actions to recover damages against the directors and officers for the benefit of the Company, and to require the Company to reform and improve its corporate governance and internal procedures. On February 13, 2015, the Kops matter was dismissed without prejudice pursuant to a stipulation entered into by the parties. The Breitman matter is presently stayed pending the outcome of a motion to dismiss in a related putative class action lawsuit, described below. The defendants believe that the allegations in the derivative complaints are without merit and intend to defend the lawsuits vigorously; however, there can be no assurance regarding the ultimate outcome of these lawsuits.

#### **Table of Contents**

#### Patent litigation:

On June 26, 2015, Immunomedics filed a complaint in the United State District Court for the District of New Jersey, against The Board of Directors of Roger Williams Medical Center ("RWMC"), Richard P. Junghans, M.D., Ph.D., Steven C. Katz, M.D., and the Office of the Board of Advisors of Tufts University School of Medicine. The complaint alleges that RWMC and Dr. Junghans breached a Material Transfer Agreement ("MTA") through which it provided to them a monoclonal antibody known as MN-14 and related materials. Those parties are alleged to have breached the MTA and to have been negligent by, among other things, using the materials beyond the agreed Research Project, sharing confidential information, failing to notify Immunomedics of intended publications prior to publishing, and refusing to return the materials upon request. Immunomedics also asserts against all defendants' claims of intentional interference with perspective economic gain and contracts, misappropriation, conversion, bailment, and several copyright violations.

#### Other matters:

Immunomedics is also a party to various claims and litigation arising in the normal course of business, which includes some or all of certain of its patents. While it is not possible to determine the outcome of these matters, the Company believes that the resolution of all such matters will not have a material adverse effect on its consolidated financial position or liquidity, but could possibly be material to its consolidated results of operations in any one accounting period.

# 12. Subsequent Events

On January 21, 2016, the Company received another \$1.9 million in proceeds as a result of a second sale of approximately \$30.3 million of New Jersey NOL's and \$0.2 million of New Jersey R&D tax credits. The receipt of the proceeds of this sale will be recorded as a tax benefit during the three-month period ending March 31, 2016.

#### **Table of Contents**

# ITEM 2.MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary Note Regarding Forward-Looking Statements

The Securities and Exchange Commission encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. Certain statements that we may make from time to time, including, without limitation, statements contained in this Quarterly Report on Form 10-Q, constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be made directly in this Quarterly Report, and they may also be made a part of this Quarterly Report by reference to other documents filed with the Securities and Exchange Commission, which is known as "incorporation by reference."

Words such as "may," "anticipate," "estimate," "expects," "projects," "intends," "plans," "believes" and words and terms of sin substance used in connection with any discussion of future operating or financial performance, are intended to identify forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, among other things: our inability to further identify, develop and achieve commercial success for new products and technologies; the possibility of delays in the research and development necessary to select drug development candidates and delays in clinical trials; the risk that clinical trials may not result in marketable products; the risk that we may be unable to obtain additional capital through strategic collaborations, licensing, issuance of convertible debt securities or equity financing in order to continue our research and secure regulatory approval of and market our drug candidates; the risk that we or any of our collaborators may be unable to secure regulatory approval of and market our drug candidates; our dependence upon pharmaceutical and biotechnology collaborations; the levels and timing of payments under our collaborative agreements; uncertainties about our ability to obtain new corporate collaborations and acquire new technologies on satisfactory terms, if at all; the development of competing products; our ability to protect our proprietary technologies; patent-infringement claims; and risks of new, changing and competitive technologies and regulations in the United States and internationally; and other factors discussed under the heading Item 1A "Risk Factors" in this Quarterly Report on Form 10-Q.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Quarterly Report or in any document incorporated by reference might not occur. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Quarterly Report or the date of the document incorporated by reference in this Quarterly Report. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by applicable law. All subsequent forward-looking statements attributable to Immunomedics, Inc. ("Immunomedics," the "Company," "we," "our" or "us"), or to any person authorized to act on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

#### Overview

Immunomedics is a clinical-stage biopharmaceutical company developing monoclonal antibody-based products for the targeted treatment of cancer, autoimmune disorders and other serious diseases. Our

#### **Table of Contents**

advanced proprietary technologies allow us to create humanized antibodies that can be used either alone in unlabeled or "naked" form, or conjugated with radioactive isotopes, chemotherapeutics, cytokines or toxins. Using these technologies, we have built a pipeline of nine clinical-stage product candidates.

Our most advanced candidate is 90Y-clivatuzumab tetraxetan. The radiolabeled antibody is in a Phase 3 registration trial in patients with advanced pancreatic cancer. We expect patient enrollment to be completed in calendar year 2016. Our portfolio of investigational products also includes antibody-drug conjugates ("ADCs") that are designed to deliver a specific payload of a chemotherapeutic directly to the tumor while reducing overall toxicities that are usually found with conventional administration of these chemotherapeutic agents. Our most advanced ADCs are sacituzumab govitecan ("IMMU-132") and labetuzumab govitecan ("IMMU-130"), which are in Phase 2 trials for a number of solid tumors and metastatic colorectal cancer ("mCRC"), respectively.

We have a research collaboration with Bayer to study epratuzumab as a thorium-227 labeled antibody. We have other ongoing collaborations in oncology in collaboration with independent cancer study groups.

We also have a number of other product candidates that target solid tumors and hematologic malignancies, as well as other diseases, in various stages of clinical and pre-clinical development. These include bispecific antibodies targeting cancers as T-cell redirecting immunotherapies, as well as bispecific antibodies for next-generation cancer and autoimmune disease therapies, created using its patented DOCK-AND-LOCK® ("DNL®") protein conjugation technology. We believe that our portfolio of intellectual property provides commercially reasonable protection for our product candidates and technologies.

The development and commercialization of successful therapeutic products is subject to numerous risks and uncertainties including, without limitation, the following:

- the type of therapeutic compound under investigation and nature of the disease in connection with which the compound is being studied;
- · our ability, as well as the ability of our partners, to conduct and complete clinical trials on a timely basis;
- the time required for us to comply with all applicable federal, state and foreign legal requirements, including, without limitation, our receipt of the necessary approvals of the U.S. Food and Drug Administration ("FDA"), if at all:
- the financial resources available to us during any particular period; and
- · many other factors associated with the commercial development of therapeutic products outside of our control. See Risk Factors in Item 1A of this Quarterly Report.

#### Research and Development

As of December 31, 2015, we employed 14 professionals in our research and development departments and 26 professionals in our pre-clinical and clinical research departments. In addition to salaries and benefits, the other costs associated with research and development include the costs associated with

#### **Table of Contents**

producing biopharmaceutical compounds, laboratory equipment and supplies, the costs of conducting clinical trials, legal fees and expenses associated with pursuing patent protection, as well as facilities costs.

At any one time our scientists are engaged in the research and development of multiple therapeutic compounds. Because we do not track expenses on the basis of each individual compound under investigation, but rather aggregate research and development costs for accounting purposes, it is not possible for investors to analyze and compare the expenses associated with unsuccessful research and development efforts for any particular fiscal period, with those associated with compounds that are determined to be worthy of further development. This may make it more difficult for investors to evaluate our business and future prospects.

#### Clinical Pipeline Update

The following is an update of the status of our clinical trials.

#### Yttrium-90-Labeled Clivatuzumab Tetraxetan

The Phase 3 PANCRIT-1 registration trial of yttrium-90-labeled clivatuzumab tetraxetan continues to enroll patients with metastatic pancreatic cancer who have received at least two prior therapies, one of which must have been a gemcitabine-containing regimen. The study is evaluating the safety and overall survival, of clivatuzumab tetraxetan labeled with 90Y plus low-dose gemcitabine and best supportive care compared to placebo plus low-dose gemcitabine and best supportive care. Repeated treatments with the combination of yttrium-90-labeled clivatuzumab tetraxetan and low-dose gemcitabine have been found to offer a survival benefit in the same late-stage setting in an earlier Phase 1b study. The PANCRIT-1 study is being conducted in the United States and Western Europe. We expect patient enrollment to be completed in calendar year 2016.

#### Antibody-Drug Conjugates (ADCs)

We have two product candidates from our proprietary ADC program that are in clinical development, focusing on the treatment of patients with metastatic solid tumors. The first ADC program, sacituzumab govitecan is an anti-TROP-2-SN-38 ADC currently being evaluated in patients with a variety of solid tumors. Labetuzumab govitecan is an anti-CEACAM5-SN-38 ADC currently in development for the treatment of mCRC.

#### Sacituzumab Govitecan or IMMU-132

Sacituzumab govitecan has received Fast Track designation from FDA for the treatment of patients with triple-negative breast cancer ("TNBC") who have failed prior therapies for metastatic disease and for patients with small-cell lung cancer ("SCLC"), or non-small-cell lung cancer ("NSCLC"). This ADC has also been designated an orphan drug by FDA for the treatment of patients with SCLC or pancreatic cancer in the U.S. and by the European Medicines Agency ("EMA") for the treatment of patients with pancreatic cancer in the European Union.

Currently, clinical development for sacituzumab govitecan focuses on a number of select types of solid cancers including TNBC, SCLC, NSCLC and certain other cancers. Interim Phase 2 results in patients with metastatic TNBC were updated at the 2015 San Antonio Breast Cancer Symposium.

Despite the late-stage setting, sacituzumab govitecan, as a single agent, produced an interim objective response rate (ORR) of 31% by RECIST 1.1 in 58 evaluable patients, with 78% of these responding patients confirmed with a follow-up computed tomography scan, including 2 patients with a complete response.

#### **Table of Contents**

Among the 60 intent-to-treat patients, the interim median progression-free survival (PFS) was 6.0 months, with 58% of these patients having experienced a PFS event. Importantly, there is a significant positive correlation between PFS and maximal tumor shrinkage relative to baseline (R=0.62, P<0.001) for the 31 patients whose cancer had progressed after reporting stable disease, partial or complete response as their best response. Median overall survival data were too early to report, with 83% of patients still alive.

Sacituzumab govitecan has an acceptable interim safety profile in the 60 mTNBC patients reported at the Symposium. The major toxicity was Grade 3 or 4 neutropenia in 15% of patients. Severe diarrhea, commonly reported with irinotecan, was rare with only 5% Grade 3/4 incidents. Moreover, repeated doses can be given over months without evoking interfering anti-sacituzumab govitecan antibodies from patients' own immune system.

We have filed a multicenter, international, randomized, open-label Phase 3 study of approximately 328 patients with mTNBC who are refractory or relapsing after at least 2 prior chemotherapies for their metastatic disease. In accordance with our Special Protocol Assessment (SPA) agreement with the FDA, the primary endpoint of the trial will be PFS, which will be measured by an independent centralized and blinded group of radiology experts who will be assessing tumor response using RECIST 1.1 criteria. Overall survival, ORR, duration of response, and time to onset of response will serve as secondary endpoints.

Certain patents relating to the protein sequence of the hRS7 antibody used in sacituzumab govitecan have a 2023 expiration in the U.S. and 2029 overseas. Other patents relating to use of hRS7 for cancer therapy, including the SN-38 conjugated form of hRS7 used in sacituzumab govitecan, extend to 2033.

#### Labetuzumab Govitecan (IMMU-130)

Our second investigational solid-tumor ADC involves our anti-CEACAM5 antibody labetuzumab, conjugated to SN-38. The agent is currently being studied in patients with mCRC who had received at least one prior irinotecan-containing regimen and had an elevated blood titer of carcinoembryonic antigen ("CEA"). Several dosing schedules were evaluated in three Phase 1 studies. Labetuzumab govitecan showed therapeutic activity in all three trials, but a more frequent dosing schedule, with administrations of the ADC once or twice-weekly for two weeks followed by a week off, appeared to be more active in patients with mCRC than when administered every other week.

In the expanded Phase 2 study, patients were being treated in 3-week cycles, receiving labetuzumab govitecan either once or twice weekly for the first two weeks followed by one week of rest. Interim median PFS of 4.4 months from 33 patients who received the ADC once a week at the 8 or 10 mg/kg dose levels was reported at the 2015 American Society of Clinical Oncology Annual Meeting. Labetuzumab govitecan was well tolerated by patients. At the optimal once-a-week doses of 8 and 10 mg/kg, grades 3 and 4 adverse events with occurrence of 5% or more included neutropenia (5% for both dose levels), and mild diarrhea (5% in the 8 mg/kg group only). This study has completed patient enrollment with patient follow-up continuing.

Although certain patents relating to labetuzumab used in labetuzumab govitecan expired in 2014 in the U.S. and in 2015 overseas, others expire in 2016. Other patents relating to use labetuzumab for cancer therapy, including the SN-38 conjugated form of labetuzumab used in labetuzumab govitecan, extend to 2033.

#### **Epratuzumab**

We have licensed epratuzumab to UCB for the treatment of all autoimmune disease indications worldwide. On July 28, 2015, UCB announced that the two Phase 3 EMBODY<sup>TM</sup> clinical trials for epratuzumab in SLE did not meet the primary clinical efficacy endpoints in either dose in both studies.

#### **Table of Contents**

We have retained the rights to epratuzumab in oncology and have a research collaboration with Bayer to study epratuzumab as a thorium-227 labeled antibody. We also have additional collaborations ongoing in oncology with independent study groups.

The IntreALL Inter-European study group is conducting a large, multicenter, international trial combining epratuzumab with chemotherapy in pediatric patients with relapsed acute lymphoblastic leukemia ("ALL") at clinical sites in Australia, Europe, and Israel. This Phase 3 study, which is partially funded by the European Commission, assesses the efficacy and safety of this combination therapy using event-free survival as the surrogate for survival, the primary endpoint. For adult patients with ALL, there is one ongoing clinical trial. The CheprALL study, sponsored by the French GRAALL study group, is a multicenter Phase 2 trial of epratuzumab combined with chemotherapy also in adult patients with relapsed ALL.

Although certain patents to the epratuzumab protein sequence expired in 2014 in the U.S. and in 2015 overseas, other issued patents to therapeutic use of epratuzumab extend to 2018-2023 for cancer and 2020 for autoimmune disease. The method of preparing concentrated epratuzumab for subcutaneous administration is covered by another patent family with an expiration date in 2032.

# Early-Stage Programs

We have additional potential products for the treatment of cancer and autoimmune diseases including veltuzumab, our anti-CD20 antibody, milatuzumab, our anti-CD74 antibody and IMMU-114, a humanized anti-HLA-DR antibody.

#### Veltuzumab

A Phase 2 study of veltuzumab in combination with 90Y-epratuzumab tetraxetan in patients with aggressive non-Hodgkin lymphoma ("NHL"), funded by a grant from the Small Business Innovation Research ("SBIR") program of the National Cancer Institute ("NCI") has completed patient enrollment with patient follow-up continuing.

In autoimmune diseases, we have studied the subcutaneous formulation of veltuzumab in patients with immune thrombocytopenia ("ITP") in a Phase 1/2 trial. This trial, designed to evaluate different dosing schedules, has completed patient accrual and patients will be followed for up to five years. The Office of Orphan Products Development of FDA has granted orphan status for the use of veltuzumab for the treatment of ITP.

We are currently evaluating various options for further clinical development of veltuzumab in ITP and other autoimmune disease indications, including pemphigus, as well as in oncology, including licensing arrangements and collaborations with outside study groups.

#### Milatuzumab

Milatuzumab is the first anti-CD74 antibody that has entered into human testing and we have completed initial Phase 1studies in patients with relapsed multiple myeloma, NHL or chronic lymphocytic leukemia ("CLL"). It has received orphan drug designation from FDA for the treatment of patients with multiple myeloma or CLL.

The anti-CD74 antibody is also being studied subcutaneously in a Phase 1b study in patients with active SLE supported by a three-year research grant from the Department of Defense with a potential funding of up to \$1.6 million.

#### **Table of Contents**

#### **IMMU-114**

IMMU-114 is a novel humanized antibody directed against an immune response target, HLA-DR, under development for the treatment of patients with B-cell cancers. HLA-DR is a receptor located on the cell surface whose role is to present foreign objects to the immune system for the purpose of eliciting an immune response. Increased presence of HLA-DR in hematologic cancers has made it a prime target for antibody therapy. The anti-HLA-DR antibody is being evaluated as a subcutaneously administered monotherapy for patients with NHL or CLL in a Phase 1 study. First results from this study were presented at the 2015 Annual Meeting of the American Society of Hematology.

Seventeen patients with a median of 2 prior therapies (range 1-7) had been enrolled. All 17 patients had failed rituximab or other anti-CD20 antibody therapies. Ten patients in the initial dose-escalation phase of the study received 200 mg IMMU-114 injections once, twice, or thrice weekly for the first 3 weeks of a 4-week cycle. All patients receive 2 consecutive treatment cycles, followed 4 weeks later by elective maintenance therapy.

While the maximum tolerated dose was not determined, with lack of toxicity and preliminary efficacy already observed at the two lowest dose levels, the twice-weekly dosing schedule was chosen for subsequent patients enrolled. Treatment response was assessed using 2007 IWG-NHL or 2008 IW-CLL criteria 4 weeks after cycle 2, then every 3 months until disease progression.

In total, five assessable patients had evidence of treatment response (stable disease, partial and complete responses), including one patient with follicular lymphoma who reported a complete response and another with stable disease, as well as one patient with diffuse large B-cell lymphoma with a partial response and two patients with CLL having partial responses.

Subcutaneous injections of IMMU-114 were well tolerated by patients, with only local skin reactions at the injection sites, which were all mild to moderate and transient. Furthermore, only one patient had evidence of immunogenicity of uncertain significance and no other cytopenias or changes in routine safety laboratory results occurred.

# Thorium-227-Labeled Epratuzumab Tetraxetan

Targeted Thorium Conjugates ("TTCs") represent a new technology directing the power of the alpha-particle selectively towards tumor cells. The high linear energy transfer of the alpha particle generated by decay of the radionuclide thorium-227 induces double-strand DNA breaks causing cell death in targeted tumor cells.

Our corporate partner, Bayer, is conducting a Phase 1 clinical trial evaluating epratuzumab labeled with thorium-227 in patients with relapsed or refractory CD22-positive NHL, with focus on patients with diffuse large B-cell lymphoma and potentially follicular lymphomas who have been previously treated with, or are not considered candidates for available therapies.

# Yttrium-90-Labeled Epratuzumab Tetraxetan

90Y-epratuzumab tetraxetan is our radiolabeled anti-CD22 investigational product for patients with NHL or ALL. As noted above, the radiolabeled antibody is currently being studied in a combination with veltuzumab in a Phase 2 clinical trial for the therapy of patients with aggressive NHL, supported by a NCI-SBIR grant. In ALL, a team from the University of Nantes, Nantes, France, is sponsoring a Phase 1/2 study to evaluate the safety and efficacy of 90Y-epratuzumab tetraxetan in patients with relapsed or refractory ALL.

#### **Table of Contents**

#### Critical Accounting Policies

For a description of our significant accounting policies, see Notes to Unaudited Condensed Consolidated Financial Statements – Note 2 Summary of Significant Accounting Policies. Of these policies, the following are considered critical to an understanding of the Company's Consolidated Financial Statements as they require the application of the most difficult, subjective and complex judgments; (i) Revenue recognition, (ii) Stock-based compensation, (iii) Research and development costs and (iv) Reimbursement of research and development costs.

# Government Regulation

#### Regulatory Compliance

Our research and development activities, including testing in laboratory animals and in humans, our manufacture of antibodies, as well as the design, manufacturing, safety, efficacy, handling, labeling, storage, record-keeping, advertising, promotion and marketing of the product candidates that we are developing and our marketed products, are all subject to stringent regulation, primarily by the FDA in the U.S. under the Federal Food, Drug, and Cosmetic Act ("FFDCA") and its implementing regulations, and the Public Health Service Act ("PHSA") and its implementing regulations, and by comparable authorities under similar laws and regulations in other countries. If for any reason we do not comply with applicable requirements, such noncompliance can result in various adverse consequences, including one or more delays in approval of, or even the refusal to approve, product licenses or other applications, the suspension or termination of clinical investigations, the revocation of approvals previously granted, as well as fines, criminal prosecution, recall or seizure of products, injunctions against shipping products and total or partial suspension of production and/or refusal to allow us to enter into governmental supply contracts.

#### **Product Approval**

In the United States, our product candidates are regulated as biologic pharmaceuticals, or biologics. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- · completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices ("GLP") regulations;
- · submission to the FDA of an Investigational New Drug Application ("IND") which must become effective before human clinical trials may begin and must be updated annually;
- · approval by an independent Institutional Review Board ("IRB") the ethics committee at each clinical site before the trial is initiated.
- · performance of adequate and well-controlled clinical trials to establish the safety, purity and potency of the proposed biologic, and the safety and efficacy of the proposed drug for each indication;
- · preparation of and submission to the FDA of a Biologics License Application ("BLA") for a new biologic, after completion of all pivotal clinical trials;
- · satisfactory completion of an FDA Advisory Committee review, if applicable;
- · a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;

#### **Table of Contents**

- · satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities to assess compliance with current Good Manufacturing Practice ("cGMP") regulations; and
- · FDA review and approval of a BLA for a new biologic, prior to any commercial marketing or sale of the product in the United States.

Preclinical tests assess the potential safety and efficacy of a product candidate in animal models. Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices ("cGCPs"), which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's IRB before the trials may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a pharmaceutical, including a biologic, is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- · Phase 1 studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.
- · Phase 2 includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational product for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the product.
- · Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product approval.

The FDA may place clinical trials on hold at any point in this process if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk. Trials may also be terminated by IRBs, which must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing authorization.

The results of the preclinical and clinical testing, along with information regarding the manufacturing of the product and proposed product labeling, are evaluated and, if determined appropriate, submitted to the FDA through a BLA. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Once the BLA submission has been accepted for filing, the FDA's standard goal is to review applications within ten months of the filing date or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from the filing date. The review process is often significantly extended by FDA requests for additional information or clarification. FDA offers certain programs, such as Fast Track designation, designed to expedite the development and review of applications for products intended for the treatment of a serious or life-threatening disease or condition. If Fast Track designation is obtained, the FDA may initiate review of sections of a BLA before the application is complete, and the product may be eligible for accelerate approval. However, receipt of Fast Track designation for a

#### **Table of Contents**

product candidate does not ensure that a product will be developed or approved on an expedited basis, and such designation may be rescinded if the product candidate is found to no longer meet the qualifying criteria.

The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, which includes determining whether it is effective for its intended use, and whether the product is being manufactured in accordance with cGMP, to assure and preserve the product's identity, strength, quality, potency and purity. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

After the FDA evaluates the BLA and conducts inspections of manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. The FDA could approve the BLA with a Risk Evaluation and Mitigation Strategy ("REMS") plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated pathway establishes legal authority for FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. In March 2015, the FDA approved Novartis's Zarxio as a biosimilar product to Amgen's Neupogen. The approval, the first biosimilar product approved for distribution in the United States, could usher in lower prices for biologic products from increased competition.

#### Post-Approval Requirements

Any products manufactured or distributed by us or on our behalf pursuant to FDA approvals are subject to continuing regulation by the FDA and certain state agencies, including requirements for record-keeping, reporting of adverse experiences with the biologic, submitting biological product deviation reports to notify the FDA of unanticipated changes in distributed products, establishment registration, compliance with cGMP standards (including investigation and correction of any deviations from cGMP), and certain state chain of distribution pedigree requirements. Additionally, any significant change in the approved product or in how it is manufactured, including changes in formulation or the site of manufacture, generally require prior FDA approval. The packaging and labeling of all products developed by us are also subject to FDA approval and ongoing regulation. Noncompliance with any regulatory requirements can result in, among other things, issuance of warning letters, civil and criminal penalties, seizures, and injunctive action. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

#### **Table of Contents**

#### Orphan Drug Act

To date, we have successfully obtained Orphan Drug designation by the FDA under the Orphan Drug Act of 1983 for epratuzumab for NHL, yttrium-90-labeled clivatuzumab tetraxetan for pancreatic cancer, sacituzumab govitecan for SCLC and pancreatic cancer, labetuzumab for ovarian, pancreatic and SCLCs, milatuzumab for multiple myeloma and CLL, and veltuzumab for ITP and pemphigus. Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same orphan indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or where the manufacturer of the approved product cannot assure sufficient quantities. As a result, there can be no assurance that our competitors will not receive approval of drugs or biologics that have a different active ingredient for treatment of the diseases for which our products and product candidates are targeted.

#### Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates being developed, and products being marketed outside of the United States. We must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of our products in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required by the FDA for BLA licensure. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, we are subject to post-approval regulatory requirements, such as those regarding product manufacturing, marketing, or distribution.

#### Other Regulatory Considerations

We are also subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, The Clean Air Act, New Jersey Department of Environmental Protection and other current and potential future federal, state, or local regulations. Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials and various radioactive compounds. We believe that our procedures comply with the standards prescribed by state and federal regulations; however, the risk of injury or accidental contamination cannot be completely eliminated.

We may also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we may market our products and product candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy, and security and physician sunshine laws and regulations.

#### **Table of Contents**

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies, based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim, including items or services resulting from a violation of the federal Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The majority of states also have anti-kickback laws, which establish similar prohibitions and, in some cases, may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating compliance of healthcare providers and manufacturers with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") also created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act ("ACA") imposes, among other things, new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers were required to begin collecting data on August 1, 2013 and submit reports to the government by March 31, 2014 and June 30, 2014, and the 90th day of each subsequent calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

#### **Table of Contents**

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act ("HITECH") and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

We are subject to the U.S. Foreign Corrupt Practices Act, which prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. Under this act, it is illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Our present and future business has been and will continue to be subject to various other laws and regulations.

# **Pricing Controls**

The levels of revenues and profitability of biopharmaceutical companies may be affected by the continuing efforts of government and third party payers to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing reimbursement or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the U. S., there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

#### Third Party Coverage and Reimbursement

In addition, in the U.S. and elsewhere, sales of therapeutic and other pharmaceutical products are dependent in part on the availability of reimbursement to the consumer from third party payers such as government and private insurance plans. Third party payers are increasingly challenging the prices charged for medical products and services. We cannot assure you that any of our products will be considered cost effective and that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a competitive and profitable basis.

# **Results of Operations**

Our results for any interim period, such as those described in the following analysis, are not necessarily indicative of the results for the entire fiscal year or any other future period.

#### **Table of Contents**

Three-Month Period Ended December 31, 2015 Compared to 2014

#### Revenues

Revenues for the three-month period ended December 31, 2015 were \$0.7 million, as compared to \$1.0 million for the three-month period ended December 31, 2014, representing a decrease of \$0.3 million, or approximately 30%. Product sales for the three-month period ended December 31, 2015 were \$0.6 million, as compared to \$0.8 million for the same period in 2014, a decline of approximately 25% due equally to lower sales volume of LeukoScan in Europe and unfavorable currency rates. Research and development revenues for the three-month periods ended December 31, 2015 and 2014 were \$0.1 million and \$0.2 million, respectively, due primarily to a decline in the number of government funded research grants.

### Costs and Expenses

Total costs and expenses for the three-month period ended December 31, 2015 were \$16.4 million, as compared to \$12.5 million for the same period in 2014, representing an increase of \$3.9 million, or approximately 31%. Research and development expenses for the three-month period ended December 31, 2015 were \$14.3 million, as compared to \$10.4 million for the same period in 2014, representing an increase of \$3.9 million, or approximately 38%. This increase was primarily due to increased product development expenses related to the Phase 3 PANCRIT-1 and the Phase 2 antibody-drug conjugates' clinical trials.

Cost of goods sold for both three-month periods ended December 31, 2015 and 2014 were \$0.1 million. Gross profit margins were approximately 89% for the three months ended December 31, 2015 as compared to approximately 91% for the three months ended December 31, 2014. Sales and marketing expenses for the three-month periods ended December 31, 2015 and 2014 were \$0.4 million and \$0.2 million, respectively. This increase was primarily due to changes in the clinical and commercial operations in Europe. General and administrative expenses were \$1.6 million for the three month period ended December 31, 2015 representing a decrease of \$0.3 million, or approximately 16%, as compared to \$1.9 million for the three month period ended December 31, 2014. This decrease is primarily attributable to approximately \$0.2 million of reduced legal and professional fees (regarding the arbitration proceedings with Takeda-Nycomed, which concluded during the 2015 fiscal year).

#### Interest Expense

Interest expense for the three-month period ended December 31, 2015 was \$1.4 million, which related to the issuance in February 2015 of \$100.0 million of 4.75% Convertible Senior Notes due in February 2020 and included amortization of debt issuance costs of \$0.2 million. There was no interest expense for the three-month period ended December 31, 2014.

Income Tax Benefit (Expense)

Income tax benefit was \$3.2 million for the three-month period ended December 31, 2015 as compared to an income tax expense of \$27 thousand for the same period in 2014. The income tax benefit relates to the sale of a portion of our New Jersey State Tax NOL's and R&D tax credits in 2015. No NOL's or R&D tax credits were sold during the three-month period ended December 31, 2014.

Net Loss Attributable to Immunomedics, Inc. Stockholders

Net loss attributable to Immunomedics, Inc. common stockholders for the three-month period ended December 31, 2015 was \$13.7 million, or \$0.15 per share, as compared to a net loss of \$11.4 million, or \$0.12

#### **Table of Contents**

per share, in the same period in 2014. The \$2.3 million increase in the net loss in the current quarter was primarily due to increased research and development cost related to clinical trials and interest expense for the convertible senior notes, partially offset by the New Jersey State tax benefit received.

Six-Month Period Ended December 31, 2015 Compared to 2014

Revenues

Revenues for the six-month period ended December 31, 2015 were \$1.4 million as compared to \$2.1 million for the same period in 2014, representing a decrease of \$0.7 million, or approximately 33%. Product sales for the six-month period ended December 31, 2015 were \$1.2 million as compared to \$1.5 million for the same period in 2014, representing a decrease of \$0.3 million, or approximately 20%, due to unfavorable fluctuations in the currency rates in Europe and lower sales volume of LeukoScan. Research and development revenues for the six-month period ended December 31, 2015 were \$0.2 million as compared to \$0.6 million for the previous year, a decline of 0.4 million or approximately 67%, due primarily to a decline in the number of government funded research grants.

#### Costs and Expenses

Total costs and expenses for the six-month period ended December 31, 2015 were \$31.2 million as compared to \$26.0 million for the same period in 2014, representing an increase of \$5.2 million, or approximately 20%. Research and development expenses for the six-month period ended December 31, 2015 were \$27.2 million as compared to \$19.8 million for the same period in 2014, representing an increase of \$7.4 million, or approximately 37%. This increase was primarily due to higher phase 3 clinical trial expenses for clivatuzumab tetraxetan and increased product development expenses related to the antibody-drug conjugates' clinical trials.

Cost of goods sold for each of the six-month periods ended December 31, 2015 and 2014 was \$0.1 million. Gross profit margins were approximately 90% for both the first six-months of fiscal 2016 and fiscal 2015. Sales and marketing expenses increased from \$0.4 million for the six-month period ended December 31, 2014 to \$0.5 million for the six-month period ended December 31, 2015. General and administrative costs were \$3.3 million for the six-month period ended December 31, 2015 and \$5.7 million for the same period in 2014 representing a decrease of \$2.4 million, or approximately 42%. This decrease is primarily attributable to approximately \$2.4 million of reduced legal and professional fees in fiscal 2016 regarding the arbitration proceedings with Takeda-Nycomed, which concluded during the 2015 fiscal year.

Interest Expense

Interest expense for the six-month period ended December 31, 2015 was \$2.8 million, which related to the issuance in February 2015 of \$100.0 million of 4.75% Convertible Senior Notes, due in February 2020 and included amortization of debt issuance costs of \$0.4 million. There was no interest expense for the six-month period ended December 31, 2014.

Income Tax Benefit (Expense)

Income tax benefit was \$3.2 million for the six-month period ended December 31, 2015 as compared to an income tax expense of \$39 thousand for the same period in 2014. The income tax benefit relates to the sale of a portion of our New Jersey State Tax NOL's and R&D tax credits in 2015. No NOL's or R&D tax credits were sold during the six month period ended December 31, 2014.

#### **Table of Contents**

Net Loss Attributable to Immunomedics, Inc. Stockholders

Net Loss Attributable to Immunomedics, Inc. stockholders for the six-month period ended December 31, 2015 was \$29.1 million or \$0.31 per share, as compared to net loss of \$23.8 million, or \$0.26 per share, for the same period in 2014, representing an increased net loss of \$5.3 million. The increase of the net loss was primarily due to increased research and development cost related to clinical trials and interest expense for the convertible senior notes, partially offset by the income tax benefit and reduced legal and professional fees.

Liquidity and Capital Resources

Discussion of Cash Flows

Cash flows from operating activities. Net cash used in operating activities for the six-month period ended December 31, 2015 was \$21.8 million as compared to \$19.6 million net cash used in operating activities for the six-month period ended December 31, 2014. The increase in cash used in operating activities in fiscal 2016 primarily resulted from a \$5.3 million increase in our net loss between the two periods under comparison (which includes \$3.2 million of cash proceeds for the income tax benefit in fiscal 2016). This increase was partially offset by non-cash expenses and a \$3.1 million increase of accounts payables and accrued expenses over the prior year end, (primarily as a result of increased phase 3 clinical trial expenses for clivatuzumab tetraxetan).

Cash flows from investing activities. Net cash provided by investing activities for the six-months ended December 31, 2015 was \$22.1 million as compared to \$15.8 million of net cash provided by investing activities for the six months ended December 31, 2014. The increase in cash flow provided by investing activities for fiscal 2016 of \$6.3 million resulted from an increase in the sales or maturities of marketable securities, net of purchases, of \$7.2 million, which were partially offset by an increase in capital expenditures of \$0.8 million.

Cash flows from financing activities. Net cash used in financing activities for the six-month period ended December 31, 2015 was \$27 thousand as compared to \$0.1 million of net cash used in financing activities for the six-months ended December 31, 2014.

Working Capital and Cash Requirements

At December 31, 2015, we had working capital of \$63.6 million, which was approximately \$27.8 million lower than the working capital of \$91.4 million at June 30, 2015. Our cash, cash equivalents and marketable securities amounted to \$76.0 million at December 31, 2015, representing a decrease of \$23.6 million from \$99.6 million at June 30, 2015. The decreases were primarily a result of our use of \$21.8 million of cash for operations and \$1.2 million used for capital expenditures.

Our budgeted cash requirements in fiscal year 2016 are expected to be in the range of \$52.0 to \$54.0 million, including interest costs of \$4.8 million for the outstanding Convertible Senior Notes as issued in February 2015. Based on our cash flow projections, we believe we have sufficient funds to continue our operations and research and development programs for at least the next twelve months. Cash requirements for research and development efforts in fiscal year 2017 are expected to decline as compared to the fiscal 2016 level, due primarily to the expected completion

of the phase 3 clinical trial for clivatuzumab tetraxetan.

#### **Table of Contents**

Future financial demands include ongoing operating expenses, Phase 3 and Phase 2 clinical trials, and further development of various clinical trial programs in fiscal 2017 and beyond.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with our currently available financial resources. These financial resources may not be adequate to sustain our operations, and we will be required to finance future cash needs through strategic licensing or collaboration agreements, the sale of additional equity and/or debt securities. However, we cannot be certain that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. The capital markets have experienced volatility in recent years, which has resulted in uncertainty with respect to availability of capital and hence the timing to meet an entity's liquidity needs. Having insufficient funds may require us to delay, scale-back or eliminate some or all of our programs or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. Additionally, if we raise funds by issuing equity securities, dilution to existing stockholders would result; and if we raise funds by incurring additional debt financing, the terms of the debt may involve future cash payment obligations and/or conversion to equity as well as restrictions that may limit our ability to operate our business.

We continue to pursue business development and licensing arrangements as a potential source of financing. These activities include any new parties who may be interested in our clinical programs as well as any licenses to our intellectual property estate. Our current partners, Bayer and UCB, S.A., State and Federal Grants, along with potential debt and equity financing may also be other sources of financing.

Actual results could differ materially from our expectations as a result of a number of risks and uncertainties, including the risks described in Item 1A Risk Factors, "Factors That May Affect Our Business and Results of Operations," and elsewhere in this Quarterly Report on Form 10-Q. Our working capital and working capital requirements are affected by numerous factors and such factors may have a negative impact on our liquidity. Principal among these are the success of product commercialization and marketing products, the technological advantages and pricing of our products, the impact of the regulatory requirements applicable to us, and access to capital markets that can provide us with the resources, when necessary, to fund our strategic priorities.

# Effects of Inflation

We do not believe that inflation has had a material impact on our business, sales or operating results during the periods presented.

# ITEM 3.QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The following discussion about our exposure to market risk of financial instruments contains forward-looking statements under the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those described due to a number of factors, including uncertainties associated with general economic conditions and conditions impacting our industry.

We may be exposed to fluctuations in foreign currencies with regard to certain agreements with service providers relating to certain clinical trials that are in process. Depending on the strengthening or weakening of the U.S. dollar, realized and unrealized currency fluctuations could be significant.

#### **Table of Contents**

#### ITEM 4.CONTROLS AND PROCEDURES

(a)Disclosure Controls and Procedures: We maintain controls and procedures designed to ensure that we are able to collect the information we are required to disclose in the reports we file with the SEC, and to record, process, summarize and disclose this information within the time periods specified in the rules promulgated by the SEC. Our Chief Executive and Chief Financial Officers are responsible for establishing and maintaining these disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) and, as required by the rules of the SEC, evaluating their effectiveness. Based on their evaluation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive and Chief Financial Officers believe that these procedures are effective to ensure that we are able to collect, process and disclose the information we are required to disclose in the reports we file with the SEC within the required time periods.

(b)Changes in Internal Controls over Financial Reporting: There were no significant changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **Table of Contents**

# PART II.OTHER INFORMATION

#### ITEM 1.LEGAL PROCEEDINGS

In the ordinary course of business, the Company may be subject to legal proceedings and claims. At this time, the Company is not a party to any legal proceedings, claims or assessments that, in managements' opinion, would have a material adverse effect on the Company's business, financial condition or results of operations.

# Shareholder complaints:

Two separate shareholder derivative complaints were filed against the Company. First, on March 24, 2014, a complaint styled Kops v. Goldenberg, et al., was filed in the Superior Court of New Jersey, Chancery Division, General Equity Part, Morris County. Second, on April 18, 2014, a complaint styled Breitman v. Sullivan, et al., was filed in the United States District Court for the District of New Jersey. The complaints alleged, among other things, that the Company and certain directors and officers breached their fiduciary duties for disseminating false and misleading information relating to the termination of the Nycomed Agreement. In particular, the complaints alleged that defendants failed to make timely disclosure concerning a dispute concerning a delay in the development of veltuzumab. On October 9, 2013, the Company announced that the Nycomed Agreement was terminated. The complaints alleged that the breaches in fiduciary duties by the directors and officers caused damages to the Company and stockholders, including a decline in value of the Company's common stock, increased investigatory and litigation costs, and exposure to civil liability as a result of a pending securities fraud class action suit. Plaintiffs brought the derivative actions to recover damages against the directors and officers for the benefit of the Company, and to require the Company to reform and improve its corporate governance and internal procedures. On February 13, 2015, the Kops matter was dismissed without prejudice pursuant to a stipulation entered into by the parties. The Breitman matter is presently stayed pending the outcome of a motion to dismiss in a related putative class action lawsuit, described below. The defendants believe that the allegations in the derivative complaints are without merit and intend to defend the lawsuits vigorously; however, there can be no assurance regarding the ultimate outcome of these lawsuits.

# Patent litigation:

On June 26, 2015, Immunomedics filed a complaint in the United State District Court for the District of New Jersey, against The Board of Directors of Roger Williams Medical Center ("RWMC"), Richard P. Junghans, M.D., Ph.D., Steven C. Katz, M.D., and the Office of the Board of Advisors of Tufts University School of Medicine. The complaint alleges that RWMC and Dr. Junghans breached a Material Transfer Agreement ("MTA") through which it provided to them a monoclonal antibody known as MN-14 and related materials. Those parties are alleged to have breached the MTA and to have been negligent by, among other things, using the materials beyond the agreed Research Project, sharing confidential information, failing to notify Immunomedics of intended publications prior to publishing, and refusing to return the materials upon request. Immunomedics also asserts against all defendants claims of intentional interference with perspective economic gain and contracts, misappropriation, conversion, bailment, and several copyright violations.

#### Other matters:

Immunomedics is also a party to various claims and litigation arising in the normal course of business, which includes some or all of certain of its patents. While it is not possible to determine the outcome of these matters, the Company believes that the resolution of all such matters will not have a material

#### **Table of Contents**

adverse effect on its consolidated financial position or liquidity, but could possibly be material to its consolidated results of operations in any one accounting period.

#### Item 1A.RISK FACTORS

Factors That May Affect Our Business and Results of Operations

Our business is subject to certain risks and uncertainties, each of which could materially and adversely affect our business, financial condition, cash flows and results of operations.

Risks Relating to Our Business, Operations and Product Development

We have a long history of operating losses and it is likely that our operating expenses will continue to exceed our revenues for the foreseeable future.

We have incurred significant operating losses since our formation in 1982. As of December 31, 2015, we had an accumulated deficit of approximately \$339 million. We continue to spend our cash resources to fund our research and development programs and, subject to adequate funding, we expect these expenses to increase for the foreseeable future. Our only significant sources of revenue in recent years have been derived from our existing licensing agreement with UCB and the collaboration agreement with Bayer. On July 28, 2015, UCB announced that the two Phase 3 EMBODY<sup>TM</sup> clinical trials for epratuzumab in SLE did not meet the primary clinical efficacy endpoints in either dose in both studies. UCB is in the process of analyzing the full set of data from both studies. The Agreement with UCB is still in effect. At this time it is unclear if any milestones will be achieved. The timing of when we are able to record licensing fee revenue from such agreements has varied historically and may result in quarterly or annual profits or losses that are not necessarily reflective of our business operations or related cash flows. There can be no assurance that we will be profitable in future quarters or other periods. Additionally, the only product sales we have earned to date have come from the limited sales of our diagnostic imaging product for which our patent protection has recently expired (which may leave us vulnerable to increased competition, for example, from generic manufacturers). In addition, we have made the strategic decision to de-emphasize sales of our diagnostic product and focus on our therapeutic pipeline. We have never had product sales of any therapeutic product. Although we may have net income from time to time based on the timing and amount of proceeds received under collaborative agreements, we expect to experience significant operating losses as we invest further in our research and development activities while simultaneously attempting to develop and commercialize our other therapeutic product candidates. If we are unable to develop commercially viable therapeutic products or to license them to third parties, it is likely that we will never achieve significant revenues or become profitable, either of which would jeopardize our ability to continue as a going concern.

We have significant future capital needs and may be unable to raise capital when needed, which could force us to delay or reduce our clinical development efforts.

We believe we have adequate cash at our current expected spending level to fund our clinical development programs through the next twelve months. However, we will require additional financial resources after we utilize our current liquid assets in order to continue our clinical development programs as is currently forecasted beyond fiscal year 2016. We are actively pursuing various financing alternatives as market conditions permit through licensing and collaborative agreements or additional potential equity or debt offerings, if necessary. We continue to evaluate various programs to raise additional capital and to seek additional revenues from the licensing of our proprietary technologies. At the present time, we are unable to determine whether any of these future activities will be successful and, if so, the terms and timing of any definitive agreements.

#### **Table of Contents**

Our most advanced therapeutic product candidates are still only in the clinical development stage, and will require us to raise capital in the future in order to fund further expensive and time-consuming studies before they can even be submitted for final regulatory approval. A failure of a clinical trial could severely harm our business and results of operations.

Clinical trials involve the administration of a product candidate to patients who are already extremely ill, making patient enrollment often difficult and expensive. Moreover, even in ideal circumstances where the patients can be enrolled and then followed for the several months or more required to complete the study, the trials can be suspended, terminated, delayed or otherwise fail for any number of reasons, including:

- · later-stage clinical trials may raise safety or efficacy concerns not readily apparent in earlier
- · trials or fail to meet the primary endpoint;
- · unforeseen difficulties in manufacturing the product candidate in compliance with all regulatory requirements and in the quantities needed to complete the trial which may become cost-prohibitive;
- · we or our collaboration partner(s) may experience delays in obtaining, or be unable to obtain, agreement for the conduct of our clinical trials from FDA, IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials:
- · while underway, the continuation of clinical trials may be delayed, suspended or terminated due to modifications to the clinical trial's protocols based on interim results obtained or changes required or conditions imposed by the FDA, an IRB, a data and safety monitoring board ("DSMB"), or any other regulatory authority;
- · our third-party contractors may fail to meet their contractual obligations to us in a timely manner;
- · FDA or other regulatory authorities may impose a clinical hold, for example based an inspection of the clinical trial operations or trial sites;
- · we or our collaboration partner(s) may suspend or cease trials in our or their sole discretion;
- · during the long trial process alternative therapies may become available which make further development of the product candidate impracticable; and
- · if we are unable to obtain the additional capital we need to fund all of the clinical trials we foresee, we may be forced to cancel or otherwise curtail such trials and other studies.

In July 2015, UCB announced that the two Phase 3 EMBODY<sup>TM</sup> clinical trials for epratuzumab in SLE did not meet the primary clinical efficacy endpoints in either dose in both studies. This announcement or substantial delay in successfully completing clinical trials for our other product candidates, sacituzumab govitecan and labetuzumab govitecan and yttrium-90-labeled clivatuzumab tetraxetan, could severely harm our business and results of operations.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, the Company may be required to report some of these relationships to FDA. FDA may conclude that a financial relationship between the company and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized.

#### **Table of Contents**

This could result in a delay in approval, or rejection, of our marketing applications by FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

Our clinical trials may not adequately show that our drugs are safe or effective, or a failure to achieve the planned endpoints could result in termination of product development.

Progression of our drug products through the clinical development process is dependent upon our trials indicating our drugs have adequate safety and efficacy in the patients being treated by achieving pre-determined safety and efficacy endpoints according to the trial protocols. Failure to achieve either of these endpoints could result in delays in our trials require the performance of additional unplanned trials or termination of any further development of the product for the intended indication. For example, with epratuzumab in SLE, the results did not meet the primary clinical efficacy endpoints in either dose in both studies. Treatment response in patients who received epratuzumab in addition to standard therapy was not statistically significant when compared to those who received placebo in addition to standard therapy.

These factors could result in delays in the development of our product candidates and could result in significant unexpected costs or the termination of programs.

Should the clinical development process be successfully completed, our ability to derive revenues from the sale of therapeutics will depend upon our first obtaining FDA as well as foreign regulatory approvals, all of which are subject to a number of unique risks and uncertainties.

Even if we are able to demonstrate the safety and efficacy of our product candidates in clinical trials, if we fail to gain timely approval to commercialize our product candidates from FDA and other foreign regulatory authorities, we will be unable to generate the revenues we will need to build our business. These approvals may not be granted on a timely basis, if at all, and even if and when they are granted, they may not cover all the indications for which we seek approval. For example, while we may develop a product candidate with the intention of addressing a large, unmet medical need, FDA may only approve the use of the drug for indications affecting a relatively small number of patients, thus greatly reducing the market size and our potential revenues. The approvals may also contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use, which could further narrow the size of the market. In certain countries, even if the health regulatory authorities approve a drug, it cannot be marketed until pricing for the drug is also approved. Finally, even after approval can be obtained, we may be required to recall or withdraw a product as a result of newly discovered safety or efficacy concerns, either of which would have a materially adverse effect on our business and results of operations.

In order to fund future operations, we will need to raise significant amounts of additional capital. Because it can be difficult for a small-cap company like ours to raise equity capital on acceptable terms, we cannot assure you that we will be able to obtain the necessary capital when we need it, or on acceptable terms, if at all.

Even if our technologies and product candidates are superior, if we lack the capital needed to bring our future products to market, we will never be successful. We have obtained the capital necessary to fund our research and development programs to date primarily from the following sources:

- · Upfront payments, milestone payments, and payments for limited amounts of our antibodies received from licensing partners;
- · Proceeds from the public and private sale of our equity or debt securities; and

#### **Table of Contents**

· Limited product sales of LeukoScan®, licenses, grants and interest income from our investments. Our budgeted cash requirements in fiscal year 2016 are expected to be in the range of \$52 to \$54 million, including interest costs of \$4.8 million for the outstanding Convertible Senior Notes issued in February 2015. Based on our cash flow projections, we believe we have sufficient funds to continue our operations and research and development programs for at least the next twelve months. Cash requirements for research and development efforts in fiscal year 2017 are expected to decline as compared to 2016, primarily due to the expected completion of the phase 3 clinical trial for clivatuzumab tetraxetan. Future financial demands include ongoing operating expenses, Phase 3 and Phase 2 clinical trials, further development of various clinical trial programs in fiscal 2017 and beyond. We will continue to require additional funding in order to fund our operations and programs. As of December 31, 2015, we have approximately \$76.0 million of cash, cash equivalents and marketable securities.

We continue to pursue business development and licensing arrangements as a potential source of financing. These activities include any new parties who may be interested in our clinical programs as well as any licenses to our intellectual property estate. Our current partner, The Bayer Group ("Bayer"), State and Federal Grants, along with potential debt and equity financing may also be other sources of financing.

Over the long term, we expect research and development activities to continue to expand and we do not believe we will have adequate cash to continue to complete development of product candidates in line with our pipeline included in our long term corporate strategy. Our capital requirements are dependent on numerous factors, including:

- The rate at which we progress our research programs and the number of product candidates we have in pre-clinical and clinical development at any one time;
- · The cost of conducting clinical trials involving patients in the U.S., Europe and possibly elsewhere;
- · Our need to establish the manufacturing capabilities necessary to produce the quantities of our product candidates we project we will need;
- The time and costs involved in obtaining FDA and foreign regulatory approvals;
- · The cost of first obtaining, and then defending, our patent claims and other intellectual property rights;
- · The ability and willingness of the holders of our 4.75% Convertible Senior Notes due 2020 to convert their Notes to Immunomedics common stock; and
- · Our ability to enter into licensing and other collaborative agreements to help offset some of these costs.

There may be additional cash requirements for many reasons, including, but not limited to, changes in our research and development plans, the need for unexpected capital expenditures or costs associated with any acquisitions of other businesses, assets or technologies that we may choose to undertake. If we deplete our existing capital resources, we will be required to either obtain additional capital quickly, or else significantly reduce our operating expenses and capital expenditures, either of which could have a material adverse effect on us.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with our available financial resources. These financial resources may not be adequate to sustain our operations and we will be required to finance future cash needs through strategic collaboration agreements, the sale of additional equity or debt securities. However, we cannot be certain that additional

#### **Table of Contents**

financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. The capital markets have experienced volatility in recent years, which has resulted in uncertainties with respect to availability of capital and hence the timing to meet an entity's liquidity needs. Having insufficient funds may require us to delay, scale-back or eliminate some or all of our programs or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. Additionally, if we raise funds by issuing equity securities, dilution to existing stockholders would result; and if we raise funds by incurring additional debt financing, the terms of the debt may involve future cash payment obligations and/or conversion to equity as well as restrictions that may limit our ability to operate our business.

If we, or our collaboration partners, cannot successfully and efficiently manufacture the compounds that make up our products and product candidates, our ability, and the ability of our collaboration partners, to sell products and conduct clinical trials will be impaired.

Our ability to conduct our pre-clinical and clinical research and development programs depends, in large part, upon our ability to manufacture our proprietary compounds in accordance with the FDA and other regulatory requirements. We have limited historical experience in manufacturing these compounds in significant quantities, and we may not be able to do so in the quantities required to commercialize these products. Any interruption in manufacturing at this site, whether by natural acts or otherwise, could significantly and adversely affect our operations, and delay our research and development programs.

We and our collaboration partners also depend on third parties to provide certain raw materials, manufacturing and processing services. All manufacturers of pharmaceutical products must comply with current Good Manufacturing Practice regulations ("cGMPs"), required by the FDA and other regulatory agencies. Such regulations address, among other matters, controls in manufacturing processes, quality control and quality assurance requirements and the maintenance of proper records and documentation. The FDA and other regulatory agencies routinely inspect manufacturing facilities. The FDA generally will issue a notice on Form 483 if it finds issues with respect to its inspections. If our manufacturing facility or those facilities of our partners and our respective contract manufacturers or processors do not comply with applicable cGMPs and other regulatory requirements, we may be subject to product liability claims, we may be unable to meet clinical demand for our products, and we could suffer delays in the progress of clinical trials for products under development.

We are dependent upon UCB for the final development and commercialization of epratuzumab for the treatment of all autoimmune disease indications worldwide, and they may not be successful.

We have licensed the exclusive worldwide rights for the treatment of all autoimmune disease indications to one of our most advanced therapeutic compounds, epratuzumab to UCB. As a result, UCB is solely responsible, and we are depending upon them, for completing the clinical development of this compound, obtaining all necessary regulatory approvals, and then commercializing and manufacturing the compounds for sale. In July 2015, UCB announced that the two Phase 3 EMBODY<sup>TM</sup> clinical trials for epratuzumab in SLE did not meet the primary clinical efficacy endpoints in either dose in both studies. As a result, their ability to commercialize this product candidate in the future, as well as our ability to commercialize other product candidates we have in development which are closely related to them, could be severely jeopardized. In such event, it is likely we could never receive any additional milestone payments or royalties that we are eligible to receive under our agreement with UCB, and our ability to fund the development and testing of our other product candidates could be adversely affected.

#### **Table of Contents**

We may not successfully establish and maintain collaborative and licensing arrangements, which could adversely affect our ability to develop and commercialize our product candidates. Our future collaboration partners may not adequately perform their responsibilities under our agreement, which could adversely affect our development and commercialization program.

A key element of our business strategy is to develop, market and commercialize our product candidates through collaborations with more established pharmaceutical companies. We may not be able to maintain or expand these licenses and collaborations or establish additional licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our product candidates.

We expect to rely at least in part on third party collaborators to perform a number of activities relating to the development and commercialization of our product candidates, including the manufacturing of product materials, the design and conduct of clinical trials for our product candidates, and potentially the obtaining of regulatory approvals and marketing and distribution of any successfully developed products. Our collaborative partners may also have or acquire rights to control aspects of our product development and clinical programs. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate. In addition, if any of these collaborative partners withdraw support for our programs or product candidates or otherwise impair their development, our business could be negatively affected. To the extent we undertake any of these activities internally, our expenses may increase.

In addition, our success depends on the performance of our collaborators of their responsibilities under these arrangements. Some potential collaborators may not perform their obligations in a timely fashion or in a manner satisfactory to us. Because such agreements may be exclusive, we may not be able to enter into a collaboration agreement with any other company covering the same product field during the applicable collaborative period. In addition, our collaborators' competitors may not wish to do business with us at all due to our relationship with our collaborators. If we are unable to enter into additional product discovery and development collaborations, our ability to sustain or expand our business will be significantly diminished.

Our future success will depend upon our ability to first obtain and then adequately protect our patent and other intellectual property rights, as well as avoiding the infringement of the rights of others.

Our future success will be highly dependent upon our ability to first obtain and then defend the patent and other intellectual property rights necessary for the commercialization of our product candidates. We have filed numerous patent applications on the technologies and processes that we use in the U.S. and certain foreign countries. Although we have obtained a number of issued U.S. patents to date, the patent applications owned or licensed by us may not result in additional patents being issued. Moreover, these patents may not afford us the protection we need against competitors with similar technologies or products. A number of jurisdictions where we have sought, or may in future choose to seek, intellectual property protection, have intellectual property laws and patent offices which are still developing. Accordingly, we may have difficulty obtaining intellectual property protection in these markets, and any intellectual property protections which we do obtain may be less protective than in the U.S., which could have an adverse effect on our operations and financial prospects.

The successful development of therapeutic products frequently requires the application of multiple technologies that may be subject to the patent or other intellectual property rights of third parties. Although

#### **Table of Contents**

we believe it is likely we will need to license technologies and processes from third parties in the ordinary course of our business, we are not currently aware of any material conflict involving our technologies and processes with any valid patents or other intellectual property rights owned or licensed by others. In the event that a third party was to claim such a conflict existed, they could sue us for damages as well as seek to prevent us from commercializing our product candidates. It is possible that a third party could successfully claim that our products infringe on their intellectual property rights. Uncertainties resulting from the litigation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Any patent litigation or other proceeding, even if resolved in our favor, would require significant financial resources and management time.

Some of our competitors may be able to sustain these costs more effectively than we can because of their substantially greater financial and managerial resources. If a patent litigation or other proceeding is resolved unfavorably to us, we may be enjoined from manufacturing or selling our products without a license from the other party, in addition to being held liable for significant damages. We may not be able to obtain any such license on commercially acceptable terms, if at all.

In addition to our reliance on patents, we attempt to protect our proprietary technologies and processes by relying on trade secret laws, nondisclosure and confidentiality agreements and licensing arrangements with our employees and other persons who have access to our proprietary information. These agreements and arrangements may not provide meaningful protection for our proprietary technologies and processes in the event of unauthorized use or disclosure of such information. In addition, our competitors may independently develop substantially equivalent technologies and processes or otherwise gain access to our trade secrets or technology, either of which could materially and adversely affect our competitive position.

Expiry of our intellectual property rights could lead to increased competition

Even where we are able to obtain and then defend patent and other intellectual property rights necessary for research, development and commercialization of our product candidates, such intellectual property rights will be for a limited term. Where patents which we own or license expire, the technology the subject of the patent may be utilized by third parties in research and development or competing products (for example, biosimilars of a patented product may be manufactured by third parties once the patent expires). While we endeavor to maintain robust intellectual property protection, as our existing issued patents expire it may materially and adversely affect our competitive position.

We face substantial competition in the biotechnology industry and may not be able to compete successfully against one or more of our competitors.

The biotechnology industry is highly competitive, particularly in the area of diagnostic and therapeutic oncology and autoimmune disease products. In recent years, there have been extensive technological innovations achieved in short periods of time, and it is possible that future technological changes and discoveries by others could result in our products and product candidates quickly becoming uncompetitive or obsolete. A number of companies, including Biogen Idec, Roche, GlaxoSmithKline, Seattle Genetics, ImmunoGen, Merck Serono, Genmab, Celgene, Amgen, Bristol-Myers Squibb, Bayer Healthcare Pharmaceuticals, Pfizer, AstraZeneca and Eli Lilly, are engaged in the development of therapeutic autoimmune and oncology products. Many of these companies have significantly greater financial, technical and marketing resources than we do. In addition, many of these companies have more established positions in the pharmaceutical industry and are therefore better equipped to develop, commercialize and market oncology and autoimmune disease products. Even some smaller competitors may obtain a significant competitive advantage over us if they are able to discover or otherwise acquire patentable inventions, form collaborative arrangements or merge with larger pharmaceutical companies. Further, even if we are able to successfully

#### **Table of Contents**

develop and commercialize products, other manufacturers operating in emerging markets may also have a competitive advantage over us with respect to competing products due to their ability to manufacture with a lower cost base.

We expect to face increasing competition from universities and other non-profit research organizations. These institutions carry out a significant amount of research and development in the field of antibody-based technologies and they are increasingly aware of the commercial value of their findings. As a result, they are demanding greater patent and other proprietary rights, as well as licensing and future royalty revenues. It is possible that such competition could come from universities with which we have, or have previously had, collaborative research and development relationships, notwithstanding our efforts to protect our intellectual property in the course of such relationships.

We may be liable for contamination or other harm caused by hazardous materials that we use in the operations of our business.

In addition to laws and regulations enforced by the FDA, we are also subject to regulation under various other foreign, federal, state and local laws and regulations. Our manufacturing and research and development programs involve the controlled use of viruses, hazardous materials, chemicals and various radioactive compounds. The risk of accidental contamination or injury from these materials can never be completely eliminated, and if an accident occurs we could be held liable for any damages that result, which could exceed our available resources.

The nature of our business exposes us to significant liability claims, and our insurance coverage may not be adequate to cover any future claims.

The use of our compounds in clinical trials and any future sale exposes us to liability claims that could be substantial. These claims might be made directly by healthcare providers, medical personnel, patients, consumers, pharmaceutical companies, and others selling or distributing our compounds. While we currently have product liability insurance that we consider adequate for our current needs, we may not be able to continue to obtain comparable insurance in the future at an acceptable cost, if at all. If for any reason we cannot maintain our existing or comparable liability insurance, our ability to clinically test and market products could be significantly impaired. Moreover, the amount and scope of our insurance coverage, as well as the indemnification arrangements with third parties upon which we rely, may be inadequate to protect us in the event of a successful product liability claim. Any successful claim in excess of our insurance coverage could materially and adversely affect our financial condition and operating results.

The loss of any of our key employees could adversely affect our operations.

We are heavily dependent upon the talents of Dr. David M. Goldenberg, our Chairman of the Board, Chief Scientific Officer, and Chief Patent Officer, and Ms. Cynthia L. Sullivan, our President and Chief Executive Officer, as well as certain other key personnel. If Dr. Goldenberg, Ms. Sullivan or any of our other key personnel were to unexpectedly leave our Company, our business and results of operations could be materially and adversely affected. In addition, as our business grows we will need to continue to attract additional management and scientific personnel. Competition for qualified personnel in the biotechnology and pharmaceutical industries is intense and we may not be successful in our recruitment efforts. If we are unable to attract, motivate and retain qualified professionals, our operations could be materially and adversely affected.

#### **Table of Contents**

Certain potential for conflicts of interest, both real and perceived, exist which could result in expensive and time-consuming litigation.

Certain members of our senior management and Board of Directors have relationships and agreements, both with us as well as among themselves and their respective affiliates, which create the potential for both real, as well as perceived, conflicts of interest. These include Dr. David M. Goldenberg, our Chairman, Chief Scientific Officer, and Chief Patent Officer, Ms. Cynthia L. Sullivan, our President and Chief Executive Officer (who is also the wife of Dr. Goldenberg), and certain companies with which we do business, including the Center for Molecular Medicine and Immunology and the Garden State Cancer Center (which operates as the clinical arm of CMMI to facilitate the translation of CMMI's research efforts in the treatment of patients), collectively defined as CMMI. For example, Dr. Goldenberg is the President and a Trustee of CMMI, a not-for-profit cancer research center that we used to conduct certain research activities. CMMI is currently in the process of dissolving. Dr. Goldenberg is also a minority stockholder, director and officer of our majority-owned subsidiary, IBC Pharmaceuticals, Inc. Dr. Goldenberg is the primary inventor of new intellectual property for Immunomedics and IBC and is largely responsible for allocating ownership between the two companies. Dr. Goldenberg also has primary responsibility for monitoring the market for incidences of potential infringement of the Company's intellectual property by third parties.

As a result of these and other relationships, the potential for both real and perceived conflicts of interest exists and disputes could arise over the allocation of funds, research projects and ownership of intellectual property rights. In addition, in the event that we become involved in stockholder litigation regarding these potential conflicts, we might be required to devote significant resources and management time defending the company from these claims, which could adversely affect our results of operations.

Given that autoimmune and cancer therapeutics such as the ones we are developing can cost upwards of \$30,000 per treatment (or more), even if our product candidates become available for sale it is likely that federal and state governments, insurance companies and other payers of health care costs will try to first limit the use of these drugs to certain patients, and may be reluctant to provide a level of reimbursement that permits us to earn a significant profit on our investment, if any.

Our ability to successfully commercialize therapeutic products will depend, in significant part, on the extent to which hospitals and physicians can obtain appropriate reimbursement levels for the cost of our products and related treatment. Third-party payers are increasingly challenging the prices charged for diagnostic and therapeutic products and related services. In addition, legislative proposals to reform health care or reduce government insurance programs may result in lower prices or the actual inability of prospective customers to purchase our products. Furthermore, even if reimbursement is available, it may not be available at price levels sufficient for us to realize a positive return on our investment.

A portion of our funding has come from federal government grants and research contracts. Due to reductions in funding, we may not be able to rely on these grants or contracts as a continuing source of funds.

During the last few years, we have generated revenues from awards made to us by the National Institutes of Health and the Department of Defense to partially fund some of our programs. We cannot rely on grants or additional contracts as a continuing source of funds. Funds available under these grants and contracts must be applied by us toward the research and development programs specified by the government rather than for all our programs generally. The government's obligation to make payments under these grants and contracts is subject to appropriation by the U.S. Congress for funding in each year. It is possible that Congress or the government agencies that administer these government research programs will continue to scale back these programs or terminate them due to their own budgetary constraints, as they have recently

#### **Table of Contents**

been doing. Additionally, these grants and research contracts are subject to adjustment based upon the results of periodic audits performed on behalf of the granting authority. Consequently, the government may not award grants or research contracts to us in the future, and any amounts that we derive from existing awards may be less than those received to date. In those circumstances, we would need to provide funding on our own, obtain other funding, or scale back or terminate the affected program. In particular, we cannot assure you that any currently-contemplated or future efforts to obtain funding for our product candidate programs through government grants or contracts will be successful, or that any such arrangements which we do conclude will supply us with sufficient funds to complete our development programs without providing additional funding on our own or obtaining other funding. Where funding is obtained from government agencies or research bodies, our intellectual property rights in the research or technology funded by the grant are typically subject to certain licenses to such agencies or bodies, which could have an impact on our utilization of such intellectual property in future.

We face a number of risks relating to the maintenance of our information systems and our use of information relating to clinical trials.

In managing our operations, we rely on computer systems and electronic communications, including systems relating to record keeping, financial information, sourcing, and back-up and the internet ("Information Systems"). Our Information Systems include the electronic storage of financial, operational, research, patient and other data. Our Information Systems may be subject to interruption or damage from a variety of causes, including power outages, computer and communications failures, system capacity constraints, catastrophic events (such as fires, tornadoes and other natural disasters), cyber risks, computer viruses and security breaches. If our Information Systems cease to function properly, are damaged or are subject to unauthorized access, we may suffer interruptions in our operations, be required to make significant investments to fix or replace systems and/or be subject to fines, penalties, lawsuits, or government action. The realization of any of these risks could have a material adverse effect on our business, financial condition and results of operations. Our clinical trials information and patient data (which may include personally identifiable information) is part of our Information Systems and is therefore subject to all of the risks set forth above, notwithstanding our efforts to code and protect such information.

Risks Related to Government Regulation of our Industry

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our future products and profitability. On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "PPACA"), which includes a number of health care reform provisions and requires most U.S. citizens to have health insurance. The new law, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, and establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Substantial new provisions affecting compliance also have been added, which may require modification of business practices with health care practitioners.

#### **Table of Contents**

In the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our future products, and we could be adversely affected by current and future health care reforms.

Our industry and we are subject to intense regulation from the U.S. Government and such other governments and quasi-official regulatory bodies where our products are and product candidates may be sold.

Both before and after regulatory approval to market a particular product candidate, including our biologic product candidates, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping related to the product are subject to extensive, ongoing regulatory requirements, including, without limitation, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements and good clinical practice requirements for any clinical trials that we conduct post-approval. As a result, we are subject to a number of governmental and other regulatory risks, which include:

- · Clinical development is a long, expensive and uncertain process; delay and failure can occur at any stage of our clinical trials:
- · Our clinical trials are dependent on patient enrollment and regulatory approvals; we do not know whether our planned trials will begin on time, or at all, or will be completed on schedule, or at all;
- · FDA or other regulatory authorities may not approve a clinical trial protocol or may place a clinical trial on hold;
- · We rely on third parties, such as consultants, contract research organizations, medical institutions, and clinical investigators, to conduct clinical trials for our drug candidates and if we or any of our third-party contractors fail to comply with applicable regulatory requirements, such as cGCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials;
- · If the clinical development process is completed successfully, our ability to derive revenues from the sale of therapeutics will depend on our first obtaining FDA or other comparable foreign regulatory approvals, each of which are subject to unique risks and uncertainties;
- There is no assurance that we will receive FDA or corollary foreign approval for any of our product candidates for any indication; we are subject to government regulation for the commercialization of our product candidates;
- · We have not received regulatory approval in the U.S. or any foreign jurisdiction for the commercial sale of any of our biologic product candidates;
  - Even if one or more of our product candidates does obtain approval, regulatory authorities may approve such product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate;
- · Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by FDA or other comparable foreign authorities;

### **Table of Contents**

- · Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with the regulatory requirements of FDA and other applicable U.S. and foreign regulatory authorities could subject us to administrative or judicially imposed sanctions;
- · Although several of our product candidates have received orphan drug designation in the U.S. and the EU for particular indications, we may not receive orphan drug exclusivity for any or all of those product candidates or indications upon approval, and even if we do obtain orphan drug exclusivity, that exclusivity may not effectively protect the product from competition;
- Even if one or more of our product candidates is approved in the U.S., it may not obtain the 12 years of exclusivity from biosimilars for which innovator biologics are eligible, and even if it does obtain such exclusivity, that exclusivity may not effectively protect the product from competition;
- · FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates, and if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained; and
- · We may be liable for contamination or other harm caused by hazardous materials used in the operations of our business.

In addition, our operations are also subject to various federal and state fraud and abuse, physician payment transparency and privacy and security laws, including, without limitation:

- The federal Anti-Kickback Statute, which prohibits, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare or Medicaid programs. This statute has been applied to pharmaceutical manufacturer marketing practices, educational programs, pricing policies and relationships with healthcare providers. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- · Federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. The government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;
- The federal HIPAA and its implementing regulations, which created federal criminal laws that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- · HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information;
- · Federal "sunshine" requirements imposed by PPACA on drug manufacturers regarding any "transfer of value" made or distributed to physicians and teaching hospitals, and any ownership and investment

#### **Table of Contents**

interests held by such physicians and their immediate family members. Failure to submit the required information may result in civil monetary penalties of up an aggregate of \$150,000 per year (and up to an aggregate of \$1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations; and

· State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require drug manufacturers to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices and financial arrangements with physicians, could be subject to challenge under one or more of such laws. Any action against us, even if we successfully defend against it, could result in the commencement of civil and/or criminal proceedings, exclusion from governmental health care programs, substantial fines, penalties, and/or administrative remedies, any of which could have an adverse effect on our financial condition and results of operations.

#### Risks Related to Our Securities

Conversion of the 4.75% Convertible Senior Notes will dilute the ownership interest of existing stockholders and could adversely affect the market price of our common stock.

The conversion of some or all of the 4.75% Convertible Senior Notes will dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon such conversion and exercise could adversely affect prevailing market prices of our common stock. In addition, the existence of the 4.75% Convertible Senior Notes may encourage short selling by market participants.

Our indebtedness and debt service obligations may adversely affect our cash flow.

As of December 31, 2015, our total consolidated indebtedness was \$113.9 million, including our obligations under our 4.75% Convertible Senior Notes. We intend to fulfill our current debt service obligations, including repayment of the principal from our existing cash and investments, as well as the proceeds from potential licensing agreements and any additional financing from equity or debt transactions. However, our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Convertible Senior Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow to meet these obligations, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive, or delaying or curtailing research and development programs. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

#### **Table of Contents**

Our common stock may be delisted from the NASDAQ Global Market, or NASDAQ.

If the bid price of our common stock falls below \$1.00 for an extended period, or we are unable to continue to meet NASDAQ's listing maintenance standards for any other reason, our common stock could be delisted from NASDAQ.

If our stock is delisted from NASDAQ, we will make every possible effort to have it listed on the Over the Counter Bulletin Board (the "OTC Bulletin Board"). If our common stock was to be traded on the OTC Bulletin Board, the Securities Exchange Act of 1934, as amended, and related SEC rules would impose additional sales practice requirements on broker-dealers that sell our securities. These rules may adversely affect the ability of stockholders to sell our common stock and otherwise negatively affect the liquidity, trading market and price of our common stock.

If our common stock would not be able to be traded on the OTC Bulletin Board, we would make every effort to have it available for trading on the National Quotation Bureau's Pink Sheets, or the Pink Sheets. The Pink Sheets market consists of security firms who act as market makers in the stocks, usually, of very small companies. The bid and asked prices are not quoted electronically, but are quoted daily in "hard copy" which is delivered to firms that subscribe. Stocks that trade in the Pink Sheets are usually not as liquid as those that trade in electronic markets and, often time, the difference between the bid and the asked prices are substantial. As a result, if our common stock were traded on the Pink Sheets, there would likely be a further negative affect on the liquidity, trading market and price of our common stock even compared to what we might suffer if we were traded on the OTC Bulletin Board.

As a result of the above, we cannot assure you that our common stock will be listed on a national securities exchange, a national quotation service, the OTC Bulletin Board or the Pink Sheets; or if it is to be listed, whether or not there would be an interruption in the trading of our common stock. We believe that the listing of our stock on a recognized national trading market, such as NASDAQ, is an important part of our business and strategy. Such a listing helps our stockholders by providing a readily available trading market with current quotations. Without that, stockholders may have a difficult time getting a quote for the sale or purchase of our stock, the sale or purchase of our stock would likely be made more difficult and the trading volume and liquidity of our stock would likely decline. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded it by other parties. In that regard, listing on a recognized national trading market will also affect our ability to benefit from the use of its operations and expansion plans, including for use in licensing agreements, joint ventures, the development of strategic relationships and acquisitions, which are critical to our business and strategy and none of which is currently the subject of any agreement, arrangement or understanding, with respect to any future financing or strategic relationship it may undertake. The delisting from NASDAQ would result in negative publicity and would negatively impact our ability to raise capital in the future.

If we were delisted from NASDAQ, we may become subject to the trading complications experienced by "Penny Stocks" in the over-the-counter market.

Delisting from NASDAQ may depress the price of our common stock such that we may become a penny stock. The SEC generally defines a penny stock as an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to specific exemptions. We continue to be listed on NASDAQ. "Penny Stock" rules require, among other things, that any broker engaging in a purchase or sale of our securities provide its customers with: (i) a risk disclosure document; (ii) disclosure of market quotations, if any; (iii) disclosure of the compensation of the broker and its salespersons in the transaction; and (iv) monthly account statements showing the market values of our securities held in the customers' accounts.

#### **Table of Contents**

A broker would be required to provide the bid and offer quotations and compensation information before effecting the transaction. This information must be contained on the customers' confirmation. Generally, brokers are less willing to effect transactions in penny stocks due to these additional delivery requirements. These requirements may make it more difficult for stockholders to purchase or sell our common stock. Because the broker, not us, prepares this information, we would not be able to assure that such information is accurate, complete or current.

We may add lease lines to finance capital expenditures and may obtain additional long term debt and lines of credit. If we issue other debt securities in the future, our debt service obligations will increase further.

Our indebtedness could have significant additional negative consequences, including, but not limited to:

- · requiring the dedication of a substantial portion of our existing cash and marketable securities balances and, if available, future cash flow from operations to service our indebtedness, thereby reducing the amount of our expected cash flow available for other purposes, including capital expenditures;
- · increasing our vulnerability to general adverse economic and industry conditions;
- · limiting our ability to obtain additional financing;
- · limiting our ability to sell assets if deemed necessary;
- · limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

We may not have the ability to raise funds necessary to purchase the Convertible Senior Notes upon a fundamental change and our future debt may contain limitations on our ability to repurchase the 4.75% Convertible Senior Notes.

Following a fundamental change as described in the indenture, holders of Convertible Senior Notes will have the right to require the Company to purchase their Convertible Senior Notes for cash. A fundamental change may also constitute an event of default or require prepayment under, and result in the acceleration of the maturity of, our other than existing indebtedness. We cannot assure you that we will have sufficient financial resources, or will be able to arrange financing, to pay the fundamental change purchase price in cash with respect to any Convertible Senior Notes surrendered by holders for purchase upon a fundamental change. In addition, restrictions in the agreements governing our then-outstanding indebtedness, if any, may not allow us to purchase the Convertible Senior Notes upon a fundamental change when required would result in an event of default with respect to the Convertible Senior Notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and purchase the Convertible Senior Notes, which could have a material and adverse impact on our financial condition and results of operations.

#### **Table of Contents**

Shares eligible for future sale may adversely affect our ability to sell equity securities.

Sales of our common stock (including the issuance of shares upon conversion of convertible debt) in the public market could materially and adversely affect the market price of shares. We have outstanding \$100 million principal amount of 4.75% Convertible Senior Notes that convert to common stock at prices equivalent to \$5.11 (subject to adjustment for certain dilutive events). Our obligation to convert the 4.75% Notes upon demand by the holders may depress the price of our common stock and also make it more difficult for us to sell equity securities or equity related securities in the future at a time and price that we deem appropriate.

As of December 31, 2015 we had 94,707,194 shares of common stock outstanding, plus (1) \$100 million of principal amount of 4.75% Convertible Senior Notes convertible into up to approximately 19,583,360 shares of common stock at the conversion rate of \$5.11 subject to adjustment as described in the indenture, (2) 5,035,021 options to purchase shares of common stock with a weighted average exercise price of \$3.33 per share, (3) 783,838 restricted stock units to purchase shares of common stock as they are vested, (4) 9,749,069 options to purchase shares of common stock under the Plan (5) 1,500,000 of restricted stock units issued to Dr. Goldenberg as part of the Amended and Restated Employment Agreement and (6) warrants to purchase 1,000,000 shares of common stock with an exercise price of \$8.00. All of the remaining 22,641,491 shares of common stock are freely tradable without restriction.

Our outstanding Convertible Senior Notes, options and warrants may adversely affect our ability to consummate future equity based financings due to the dilution potential to future investors.

Due to the number of shares of common stock we are obligated to issue pursuant to outstanding Convertible Senior Notes, options and warrants, potential investors may not purchase our future equity offerings at market price because of the potential dilution such investors may suffer as a result of the exercise of the outstanding Convertible Senior Notes, options and warrants.

Our outstanding 4.75% Convertible Senior Notes may adversely affect our ability to consummate future equity based financings due to the restrictive covenants contained in the Indenture pursuant to which the 4.75% Notes were issued.

Holders of our 4.75% Notes have certain rights that may inhibit our ability to raise additional capital. Those rights include (a) full ratchet anti dilution protection in the event we sell securities at a price lower than the applicable conversion or exercise price of the 4.75% Notes and (b) the right to pro rata participation in any future financing.

The market price of our common stock has fluctuated widely in the past, and is likely to continue to fluctuate widely based on a number of factors, many of which are beyond our control.

The market price of our common stock has been, and is likely to continue to be, highly volatile. Furthermore, the stock market and the market for stocks of relatively small biopharmaceutical companies like ours have from time to time experienced, and likely will again experience, significant price and volume fluctuations that are unrelated to actual operating performance.

#### **Table of Contents**

From time to time, stock market analysts publish research reports or otherwise comment upon our business and future prospects. Due to a number of factors, we may fail to meet the expectations of securities analysts or investors and our stock price would likely decline as a result. These factors include:

- · Announcements by us, our current collaboration partners, any future alliance partners or our competitors of pre-clinical studies and clinical trial results, regulatory developments, technological innovations or new therapeutic products, product sales, new products or product candidates and product development timelines;
- · The formation or termination of corporate alliances;
- · Developments in patent or other proprietary rights by us or our respective competitors, including litigation;
- · Developments or disputes concerning our patent or other proprietary rights, and the issuance of patents in our field of business to others;
- · Government regulatory action;
- · Period-to-period fluctuations in the results of our operations; and
- · Developments and market conditions for emerging growth companies and biopharmaceutical companies, in general. In addition, Internet "chat rooms" have provided forums where investors make predictions about our business and prospects, oftentimes without any real basis in fact, that readers may trade on.

In the past, following periods of volatility in the market prices of the securities of companies in our industry, securities class action litigation has often been instituted against those companies. Please see Item 3 ("Legal Proceedings") for a description of such litigation. If we face such litigation in the future, it would result in substantial costs and a diversion of management's attention and resources, which could negatively impact our business.

Our principal stockholder can significantly influence all matters requiring the approval by our stockholders.

As of December 31, 2015, Dr. David M. Goldenberg, our Chairman of the Board, Chief Scientific Officer and Chief Patent Officer, together with certain members of his family, including Ms. Cynthia L. Sullivan, our President and Chief Executive Officer, who is Dr. Goldenberg's wife, and other affiliates, controlled the right to vote approximately 8% of our outstanding common stock and approximately 7% of our fully diluted common stock. As a result of this voting power, Dr. Goldenberg has the ability to significantly influence the outcome of substantially all matters that may be put to a vote of our stockholders, including the election of our directors.

There are limitations on the liability of our directors, and we may have to indemnify our officers and directors in certain instances.

Our certificate of incorporation limits, to the maximum extent permitted under Delaware law, the personal liability of our directors for monetary damages for breach of their fiduciary duties as directors. Our bylaws provide that we will indemnify our officers and directors and may indemnify our employees and other agents to the fullest extent permitted by law. These provisions may be in some respects broader than the

#### **Table of Contents**

specific indemnification provisions under Delaware law. The indemnification provisions may require us, among other things, to indemnify such officers and directors against certain liabilities that may arise by reason of their status or service as directors or officers (other than liabilities arising from willful misconduct of a culpable nature), to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified and to obtain directors' and officers' insurance. Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify a director, officer, employee or agent made or threatened to be made a party to an action by reason of the fact that he or she was a director, officer, employee or agent of the corporation or was serving at the request of the corporation, against expenses actually and reasonably incurred in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Delaware law does not permit a corporation to eliminate a director's duty of care and the provisions of our certificate of incorporation have no effect on the availability of equitable remedies, such as injunction or rescission, for a director's breach of the duty of care.

We believe that our limitation of officer and director liability assists us to attract and retain qualified employees and directors. However, in the event an officer, a director or the board of directors commits an act that may legally be indemnified under Delaware law, we will be responsible to pay for such officer(s) or director(s) legal defense and potentially any damages resulting there from. Furthermore, the limitation on director liability may reduce the likelihood of derivative litigation against directors and may discourage or deter stockholders from instituting litigation against directors for breach of their fiduciary duties, even though such an action, if successful, might benefit our stockholders and us. Given the difficult environment and potential for incurring liabilities currently facing directors of publicly-held corporations, we believe that director indemnification is in our and our stockholders' best interests because it enhances our ability to attract and retain highly qualified directors and reduce a possible deterrent to entrepreneurial decision-making.

Nevertheless, limitations of director liability may be viewed as limiting the rights of stockholders, and the broad scope of the indemnification provisions contained in our certificate of incorporation and bylaws could result in increased expenses. Our board of directors believes, however, that these provisions will provide a better balancing of the legal obligations of, and protections for, directors and will contribute positively to the quality and stability of our corporate governance. Our board of directors has concluded that the benefit to stockholders of improved corporate governance outweighs any possible adverse effects on stockholders of reducing the exposure of directors to liability and broadened indemnification rights.

We are exposed to potential risks from legislation requiring companies to evaluate controls under Section 404 of the Sarbanes-Oxley Act.

The Sarbanes-Oxley Act requires that we maintain effective internal controls over financial reporting and disclosure controls and procedures. Among other things, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on, and our independent registered public accounting firm to attest to, our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act ("Section 404"). Compliance with Section 404 requires substantial accounting expense and significant management efforts. Our testing, or the subsequent review by our independent registered public accounting firm, may reveal deficiencies in our internal controls that would require us to remediate in a timely manner so as to be able to comply with the requirements of Section 404 each year. If we are not able to comply with the requirements of Section 404 in a timely manner each year, we could be subject to sanctions or investigations by the SEC, the NASDAQ GMS or other regulatory authorities that would require additional financial and management resources and could adversely affect the market price of our common stock.

## **Table of Contents**

We do not intend to pay dividends on our common stock. Until such time as we pay cash dividends our stockholders, must rely on increases in our stock price for appreciation.

We have never declared or paid dividends on our common stock. We intend to retain future earnings to develop and commercialize our product candidates and therefore we do not intend to pay cash dividends in the foreseeable future. Until such time as we determine to pay cash dividends on our common stock, our stockholders must rely on increases in the market price of our common stock for appreciation.

### **ITEM 6.EXHIBITS**

The exhibits required by Item 601 of Regulation S-K are included with this Form 10-Q and are listed on the "Exhibit Index" immediately following the Signatures.

## **Table of Contents**

### **SIGNATURES**

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

## IMMUNOMEDICS, INC.

February 3, 2016 By: /s/ Cynthia L. Sullivan

Cynthia L. Sullivan

President and Chief Executive

Officer

(Principal Executive Officer)

February 3, 2016 By: /s/ Peter P. Pfreundschuh

Peter P. Pfreundschuh
Vice President, Finance and
Chief Financial Officer
(Principal Financial and
Accounting Officer)

# Table of Contents

# **EXHIBIT INDEX**

Exhibit Number	Description of Document
10.1	Amendment, dated November 30, 2015, to the Amended and Restated Employment Agreement, entered into on July 14, 2015 and effective as of July 1, 2015, between the Company and Dr. David M. Goldenberg.*
31.1	Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.*
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following financial information from this Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2015, formatted in XBRL (eXtensible Business Reporting Language) filed electronically herewith: (i) the Condensed Consolidated Balance Sheets; (ii) the Condensed Consolidated Statements of Comprehensive Loss; (iii) the Condensed Consolidated Statements of Cash Flows; and, (iv) the Notes to Unaudited Condensed Consolidated Financial Statements.
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.
*Filed herewith.	