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IMMUNOMEDICS INC Form 10-Q November 04, 2015 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 September 30, 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)

Delaware (State or other jurisdiction of

61-1009366 (I.R.S. Employer

incorporation or organization)

**Identification No.)** 

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 x 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). x 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):

Large Accelerated Filer "

Accelerated Filer

Х

Non-Accelerated Filer "

Smaller Reporting Company "

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes " No x

The number of shares of the registrant s common stock outstanding as of November 3, 2015 was 94,639,981.

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# IMMUNOMEDICS, INC.

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# IMMUNOMEDICS, INC. AND SUBSIDIARIES

### CONDENSED CONSOLIDATED BALANCE SHEETS

# (UNAUDITED)

	Se	ptember 30, 2015	June 30, 2015
ASSETS		2013	2013
Current Assets:			
Cash and cash equivalents	\$	11,785,074	\$ 13,452,775
Marketable securities		73,703,229	86,165,532
Accounts receivable, net of allowance for doubtful accounts of \$71,624 at			
September 30, 2015 and \$54,177 at June 30, 2015		489,107	345,627
Inventory		539,184	584,424
Other receivables		85,643	857,068
Prepaid expenses		1,725,132	1,136,103
Other current assets		649,267	945,673
Total current assets		88,976,636	103,487,202
Property and equipment, net of accumulated depreciation of \$28,059,136 and			
\$27,891,272 at September 30, 2015 and June 30, 2015, respectively		2,763,914	2,241,838
Other long-term assets		50,566	50,566
		·	
Total Assets	\$	91,791,116	\$ 105,779,606
LIABILITIES AND STOCKHOLDERS DEFICIT			
Current Liabilities:			
Accounts payable and accrued expenses	\$	11,985,641	\$ 11,808,223
Deferred revenues	·	307,913	271,667
		,	,
Total current liabilities		12,293,554	12,079,890
Convertible senior notes  net of unamortized debt issuance costs of		, ,	, ,
\$3,192,968 at September 30, 2015 and \$3,375,423 at June 30, 2015		96,807,032	96,624,577
Other liabilities		1,624,639	1,599,760
Commitments and Contingencies		, ,	, ,
Stockholders Deficit:			
Preferred stock, \$0.01 par value; authorized 10,000,000 shares; no shares			
issued and outstanding at September 30, 2015 and at June 30, 2015			
Common stock, \$0.01 par value; authorized 155,000,000 shares; issued			
94,674,706 shares and outstanding 94,639,981 shares at September 30, 2015;			
and issued 94,546,578 shares and outstanding 94,511,853 shares at June 30,			
2015		946,746	945,465
Capital contributed in excess of par		306,183,459	305,229,354

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Treasury stock, at cost, 34,725 shares at September 30, 2015 and at June 30,

Treasury stock, at cost, 54,725 shares at September 50, 2015 and at rune 50,		
2015	(458,370)	(458,370)
Accumulated deficit	(324,861,826)	(309,468,004)
Accumulated other comprehensive loss	(109,927)	(161,092)
•		
Total Immunomedics, Inc. stockholders deficit	(18,299,918)	(3,912,647)
Noncontrolling interest in subsidiary	(634,191)	(611,974)
·	, , ,	, , ,
Total stockholders deficit	(18,934,109)	(4,524,621)
	, , , ,	
Total Liabilities and Stockholders Deficit	\$ 91,791,116	\$ 105,779,606

See accompanying notes to unaudited condensed consolidated financial statements

# IMMUNOMEDICS, INC. AND SUBSIDIARIES

### CONDENSED CONSOLIDATED STATEMENTS OF

### **COMPREHENSIVE LOSS**

# (UNAUDITED)

	Three months ended September 30,			30,
		2015		2014
Revenues:		-01-10		
Product sales	\$	581,248	\$	727,633
License fee and other revenues		10,825		
Research and development		138,805		344,365
Total revenues		730,878		1,071,998
Costs and Expenses:				
Costs of goods sold		58,264		76,286
Research and development	1	12,913,130		9,392,017
Sales and marketing		143,521		228,637
General and administrative		1,724,294		3,819,192
Total costs and expenses	1	14,839,209		13,516,132
Operating loss		14,108,331)	(	12,444,134)
Interest expense		(1,369,955)		25.072
Interest and other income, net		91,958		25,072
Foreign currency transaction loss		(10,461)		(11,737)
Loss before income tax expense	(1	15,396,789)	(	12,430,799)
Income tax expense		(19,250)		(11,963)
Net loss	(1	15,416,039)	(	12,442,762)
Less: Net loss attributable to noncontrolling interest		(22,217)		(32,342)
Net loss attributable to Immunomedics, Inc. stockholders	<b>\$</b> (1	15,393,822)	\$(	12,410,420)
Loss per common share attributable to Immunomedics, Inc. stockholders, (basic and diluted)	\$	(0.16)	\$	(0.13)
Weighted average shares used to calculate loss per common share, (basic and diluted)	9	94,595,826		93,098,202

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Other comprehensive income (loss), net of tax:		
Foreign currency translation adjustments	17,468	(178, 130)
Unrealized gain (loss) on available-for-sale securities	33,697	(4,452)
Other comprehensive income (loss)	51,165	(182,582)
Comprehensive loss	(15,364,874)	(12,625,344)
Less comprehensive loss attributed to noncontrolling interest	(22,217)	(32,342)
Net comprehensive loss attributable to Immunomedics, Inc.	\$ (15,342,657)	\$ (12,593,002)

See accompanying notes to unaudited condensed consolidated financial statements

# IMMUNOMEDICS, INC. AND SUBSIDIARIES

### CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

# (UNAUDITED)

	Three Months Ended September 30,		
	2015	2014	
Cash flows used in operating activities:			
Net loss	\$ (15,416,039)	\$ (12,442,762)	
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	167,865	140,817	
Amortization of deferred revenue	(10,825)	3,147	
Amortization of bond premiums	205,756	135,438	
Amortization of debt issuance costs	182,455		
Amortization of deferred rent	24,879	24,879	
Gain from the sales of marketable securities	(1,844)	(7,215)	
Increase (decrease) in allowance for doubtful accounts	17,447	(2,072)	
Non-cash expense related to stock compensation	896,687	561,110	
Changes in other operating assets and liabilities	584,152	2,479,760	
Net cash used in operating activities	(13,349,467)	(9,106,898)	
Cash flows provided by investing activities:			
Proceeds from sales of marketable securities	14,292,088	8,196,588	
Purchases of marketable securities	(2,000,000)		
Purchases of property and equipment	(689,941)	(331,750)	
Net cash provided by investing activities	11,602,147	7,864,838	
Cash flows provided by (used in) financing activities:			
Exercise of stock options, net	142,179		
Tax withholding payments for stock compensation	(83,479)	(86,571)	
Net cash provided by (used in) financing activities	58,700	(86,571)	
Effect of changes in exchange rates on cash and cash equivalents	20,919	(187,388)	
Net decrease in cash and cash equivalents	(1,667,701)	(1,516,019)	
Cash and cash equivalents, beginning of period	13,452,775	6,961,494	
Cash and cash equivalents, end of period	\$ 11,785,074	\$ 5,445,475	

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# Supplemental disclosure of cash flow information:

Interest paid \$ 2,427,778 \$

See accompanying notes to unaudited condensed consolidated financial statements.

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#### 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 audit 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 Darmstadt, 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 month period ended September 30, 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

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technologies and regulations in the United States and internationally.

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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 September 30, 2015, the Company had cash, cash equivalents and marketable securities totaling \$85.5 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, as well as for expenses for the ongoing Phase 2 expansion ADC clinical trials (sacituzumab govitecan and labetuzumab govitecan). For the three-month period ended September 30, 2015 the Company utilized cash, cash equivalents and marketable securities aggregating \$13.3 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 partner, The Bayer Group (Bayer), 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.

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#### 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) income.

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<sup>®</sup>, 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 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.

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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 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 three-month periods ended September 30, 2015 and 2014:

	<b>Three-Month Period Ended</b>		
	September 3	30,	
	2015	2014	
Expected dividend yield	0%	0%	
Expected option term (years)	5.03	5.07	
Expected stock price volatility	56%	61%	
Risk-free interest rate	1.51% - 1.61%	1.60%	

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 September 30, 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. 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.

Income taxes were provided for profitable foreign jurisdictions at the estimated annual tax rate during the three-month periods ended September 30, 2015 and 2014. The Company s U.S. operations reported a net loss for the three-month periods ended September 30, 2015 and 2014, resulting in a tax benefit that was fully offset by a valuation allowance.

The Company has no liability for uncertain tax positions as of September 30, 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 month periods ended September 30, 2015 and 2014. The common stock equivalents excluded from the diluted per share calculation are 27,839,015 and 7,461,763 shares at September 30, 2015 and 2014, respectively.

#### Net Comprehensive Loss

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

#### Reclassification

Certain prior period balances have been reclassified to conform to the current period presentation.

#### 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.

### 3. Marketable Securities

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

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Fair Value
September 30, 2015			, , ,	
U.S. Treasury Bonds	\$ 10,659	\$ 14	\$	\$ 10,673
Certificate of Deposits	8,000	4		8,004
U.S. Government Sponsored Agencies	33,300	34	(1)	33,333
Corporate Debt Securities	21,699	4	(10)	21,693
	\$ 73,658	\$ 56	\$ (11)	\$ 73,703

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

		Net	Carrying	
	Fair Value	Value Amour		
Due within one year	\$ 48,271	\$	48,436	
Due after one year through five years	25,432		25,597	
	\$ 73,703	\$	74.033	

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

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Fair Value
June 30, 2015				
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):

Fair Value

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			Net Ca		
			Α	mount	
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% will be payable 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 September 30, 2015.

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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 or issuing or repurchasing its other securities. 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 for the three-month period ended September 30, 2015 including amortization of debt issuance costs of \$0.2 million.

#### 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 September 30, 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.

Financial instruments recorded on the condensed consolidated balance sheets as of September 30, 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.

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Government and agency securities).

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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)			
<b>September 30, 2015</b>	Level 1	Level 2	Level 3	Total
Money Market Funds	\$ 8,702	\$	\$	\$ 8,702
Marketable Securities:				
U.S. Treasury Bonds	10,673			10,673
Certificate of Deposits	8,004			8,004
U.S. Government Sponsored Agencies	33,333			33,333
Corporate Debt Securities	21,693			21,693
Total	\$ 82,405	\$	\$	\$82,405

	(\$ in thousands)			
June 30, 2015	Level 1	Level 2	Level 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.

#### **Convertible Senior Notes**

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

As of September 30, 2015 As of June 30, 2015

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	Carrying	Estimated	Carrying	Estimated
	Amount	Fair Value	Amount	Fair Value
Convertible Senior Notes	\$ 96,807	\$ 70,610	\$ 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) Income

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

	Currency Translation Adjustments	Net Unrealized Gains (Losses) on Available- for-Sale Securities	Accumulated Other Comprehensive (Loss) Income
Balance, July 1, 2015 Other comprehensive income before reclassifications	\$ (172,693) 17,468	\$ 11,601 35,541	\$ (161,092) 53,009
Amounts reclassified from accumulated other comprehensive income (a)		(1,844)	(1,844)
Net current-period other comprehensive income	17,468	33,697	51,165
Balance, September 30, 2015	\$ (155,225)	\$ 45,298	\$ (109,927)
Balance, July 1, 2014 Other comprehensive (loss) income before reclassifications	\$ 261,924 (178,130)	\$ (87) 2,763	\$ 261,837 (175,367)
Amounts reclassified from accumulated other comprehensive (loss) income <sup>(a)</sup>		(7,215)	(7,215)
Net current-period other comprehensive loss	(178,130)	(4,452)	(182,582)
Balance, September 30, 2014	\$ 83,794	\$ (4,539)	\$ 79,255

All components of accumulated other comprehensive income 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

For the three-month periods ended September 30, 2015 and 2014, \$1,844 and \$7,215 was reclassified from accumulated other comprehensive income to interest and other income, respectively.

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.

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 September 30, 2015, there were 17,179,911 shares of common stock reserved for possible future issuance under the Plan, both currently outstanding (7,255,655 shares) and which were available to be issued for future grants (9,924,256 shares).

The weighted average fair value at the date of grant for options granted during the three-month periods ended September 30, 2015 and 2014 were \$0.87 and \$1.75 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 three-month period ended September 30, 2015 is summarized as follows:

	Shares	Av Ex	ighted erage ercise Price	Weighted Average Remaining Contractual Life	Int V	gregate trinsic 'alue 000 s)
Outstanding, July 1, 2015	4,525,340	\$	3.48			
Granted	484,147	\$	1.78			
Exercised	(53,250)	\$	2.67			
Cancelled or forfeited	(3,500)	\$	4.09			
Outstanding, September 30, 2015	4,952,737	\$	3.32	3.72	\$	4,550
Exercisable, September 30, 2015	3,285,794	\$	3.29	2.57	\$	4,550

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A summary of the Company s non-vested restricted and performance stock units at September 30, 2015, and changes during the three-month period ended September 30, 2015 are presented below:

	Weighted-Averag per Share of NumbeMarket Value on	
	of	Grant
<b>Outstanding Non-Vested Restricted and Performance Stock Units</b>	Awards	Date
Non-vested at July 1, 2015	706,881	\$4.30
Restricted Units Granted <sup>(a)</sup>	214,205	\$1.76
Restricted Units Granted vesting based on certain market condition(8)	1,500,000	\$ 2.28 <sup>(c)</sup>
Vested/Exercised	(118,168)	\$ 3.78
Non-vested at September 30, 2015	2,302,918	\$ 2.78

- (a) For the three-month period ended September 30, 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.
- (b) For the three-month period ended September 30, 2015, 1,500,000 restricted stock units were awarded to the Company s Chairman, Chief Scientific Officer and Chief Patent Officer.
- Represents fair value on date of grant determined by using Monte Carlo simulation technique.

The Company has 3,969,861 non-vested options, restricted stock units and performance stock units outstanding as of September 30, 2015. As of September 30, 2015, there was \$7.8 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 2.73 years. The Company recorded \$0.9 million and \$0.6 million for total stock-based compensation expense for employees, executive officers and non-employee Board members for the three-month periods ended September 30, 2015 and 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 \$45 thousand for stock-based compensation expense for these non-employee Board members restricted stock units for each of the three-month periods ended September 30, 2015 and 2014. 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 September 30, 2015, there was \$1.4 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 2.7 years. The Company recorded \$0.2 million for stock-based compensation expense for restricted stock units for each of the three-month periods ended September 30, 2015 and 2014.

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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

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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 \$0.2 million for the stock-based compensation for the three-month period ended September 30, 2015 for this agreement. There is \$3.2 million of total unrecognized compensation cost related to these non-vested Restricted Stock Units granted as of September 30, 2015. That cost is being recognized over a remaining weighted-average period of 2.8 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, 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 three-month period ended September 30, 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 2014, 116,959 units were awarded from achieving two performance milestones. As of September 30, 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 \$32 thousand for the stock-based compensation for the three-month periods ended September 30, 2015 and 2014, respectively. There is \$0.4 million of total unrecognized compensation cost related to these non-vested Performance Units granted as of September 30, 2015. That cost is being recognized over a weighted-average period of 2.2 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-months ended September 30, 2015 and 2014 (\$ in thousands):

As of

	and for the three-months ended September 30, 2015			
	United			
	States	Europe	Total	
Total assets	\$ 89,852	\$ 1,939	\$ 91,791	
Property and equipment, net	2,756	8	2,764	
Revenues	150	581	731	
(Loss) income before income tax expense	(15,427)	30	(15,397)	

As of and for the three-months ended
<b>September 30, 2014</b>

	United	United		
	States	Europe	Total	
Total assets	\$ 35,017	\$ 2,799	\$ 37,816	
Property and equipment, net	2,086		2,086	
Revenues	368	704	1,072	
(Loss) income before income tax expense	(12,455)	24	(12,431)	

#### 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 \$9 thousand and \$10 thousand of legal expenses on behalf of CMMI for patent related matters for each of the three-month periods ended September 30, 2015 and 2014. 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-month periods ended September 30, 2015 and 2014, Dr. Goldenberg received approximately \$22 thousand and \$21 thousand, respectively, in compensation for his services to IBC.

### 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 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 September 30, 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 September 30, 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 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 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.

# 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.

A putative class action lawsuit, styled *Nasyrova v. Immunomedics, Inc.*, was filed on February 27, 2014, in the United States District Court for the District of New Jersey. The lawsuit alleged that the Company and certain of its current and former officers and directors failed to disclose and/or made material misstatements in the Company s public filings relating to the termination of the Nycomed Agreement. In particular, the complaint 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 complaint alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. On July 15, 2015, the Court granted the motion to dismiss the second amended complaint with prejudice. The Court s opinion concluded that the Company had no duty to make the disclosure of information concerning the agreement at an earlier time and that there was no misstatement or omission sufficient to support the claim. The Court ordered this action closed.

# 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.

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# 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 term 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 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 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, to which we retain worldwide rights for all indications, is  $^{90}$ Y-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 toxic effects 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® (DNP) 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**

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As of September 30, 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 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 <sup>90</sup>Y 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 involves the expansion of the number of patients with select types of solid cancers including TNBC, SCLC, NSCLC and certain other cancers. Interim Phase 2 results were presented at the 2015 World ADC San Diego conference.

The presentation on TNBC focused on those patients who relapsed after 2 or more prior lines of therapy that included taxane, a class of chemotherapy agents used to treat solid cancers, such as breast, gastric, head and neck, lung, ovarian, pancreatic, and prostate. At the time of this analysis, 56 enrolled patients had received sacituzumab govitecan at the optimal dose of 10 mg/kg given on days 1 and 8 of a 3-week cycle, and in some patients the therapy continued for many months. The median number of prior lines of therapy for the patients enrolled with metastatic TNBC was 5 (range, 2 12).

Treatment response, assessed by computed tomography (CT) according to the rules set by the Response Evaluation Criteria In Solid Tumors (RECIST 1.1), was available for 52 patients. The objective response rate was 29% (15/52), with 2 confirmed complete responses. The interim median progression-free survival (PFS), a measure of time patients are living without their cancer progressing, was 7.0 months, which appears to be longer than the best PFS results in this patient setting achieved by currently-used agents. Forty-six percent of these TNBC patients had experienced a PFS event. Overall survival (OS) data were too early to report because 86% of patients are still alive.

For metastatic lung cancers, a total of 33 patients with NSCLC, having received a median of 3 (range, 1 7) prior therapies, were enrolled to receive sacituzumab govitecan at the 8.0 mg/kg or 10 mg/kg dose level. Among the 29 patients that were assessable, an objective response (partial response) rate of 28% (8/29) was observed, including patients with both squamous cell and adenocarcinoma NSCLC types. For the 25 patients at the 10 mg/kg dose, the interim median PFS was 3.8 months, with 48% of patients in this dose group having experienced a PFS event.

In SCLC, of the 27 patients, with a median of 3 prior therapies (range 1 5), enrolled at the doses of 8.0 mg/kg and 10 mg/kg, 25 were assessable for response. Six patients achieved a partial response (objective response rate = 24%). Interim median PFS for the 12 patients at the 10 mg/kg dose level was 3.6 months and 83% of patients had experienced a PFS event. Since 96% of NSCLC patients and 100% of SCLC patients were still alive at the time of analysis, OS data at the optimal dose of 10 mg/kg are too early to report.

Results on 15 patients with metastatic urothelial cancers, mostly urinary bladder cancers, were also presented for the first time. At the time of analysis, 6 of 11 patients who relapsed to a prior platinum-containing therapy and evaluable by CT achieved a partial response (objective response rate = 55%), with 5 patients still continuing treatment.

Sacituzumab govitecan continues to demonstrate a highly tolerable safety profile. Among the 261 patients enrolled to-date, only 8 patients had reported adverse events that temporarily interrupted the infusion. In the 118 patients receiving the ADC at the dose of 10 mg/kg, the major toxicity reported was Grades 3 or 4 neutropenia in 20% of patients.

Certain patents relating to the protein sequence of the hRS7 antibody used in sacituzumab govitecan have a 2017 expiration in the U.S. and 2023 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.

Certain patents relating to labetuzumab used in labetuzumab govitecan expire in 2014-2016. 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 clinical trials for epratuzumab in SLE did not meet the primary clinical efficacy endpoints in either dose in both studies.

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  $^{90}$ Y-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 are studying 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

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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.

#### 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

<sup>90</sup>Y-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 <sup>90</sup>Y-epratuzumab tetraxetan in patients with relapsed or refractory ALL.

#### 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.

#### 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;

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.

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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 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.

# 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.

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.

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.

# Three-Month Period Ended September 30, 2015 Compared to 2014

#### Revenues

Revenues for the three-month period ended September 30, 2015 were \$0.7 million, as compared to \$1.1 million for the three-month period ended September 30, 2014. Product sales for the three-month period ended September 30, 2015 were \$0.6 million, as compared to \$0.7 million for the same period in 2014, a decline due primarily to unfavorable currency rates on LeukoScan sales in Europe. Research and development revenues for the three-month periods ended September 30, 2015 and 2014 were \$0.1 and \$0.3 million, respectively. The reduction of research and development revenue of \$0.2 million is primarily due to a decline in the number of government funded research grants.

# Costs and Expenses

Total costs and expenses for the three-month period ended September 30, 2015 were \$14.8 million, as compared to \$13.5 million for the same period in 2014, representing an increase of \$1.3 million or 10%. Research and development expenses for the three-month period ended September 30, 2015 were \$12.9 million, as compared to \$9.4 million for the same period in 2014, an increase of \$3.5 million, or 37%. 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 September 30, 2015 and 2014 were \$0.1 million. Gross profit margins were 90% for both periods. Sales and marketing expenses for the three-month periods ended September 30, 2015 and 2014 were \$0.1 million and \$0.2 million, respectively. General and administrative expenses were \$1.7 million for the three month period ended September 30, 2015 representing a decrease of \$2.1 million, or 55%, as compared to \$3.8 million for the three month period ended September 30, 2014. This decrease is primarily attributable to approximately \$2.4 million of reduced legal and professional fees, (principally legal 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 September 30, 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 September 30, 2014.

Net Loss Attributable to Immunomedics, Inc.

Net loss attributable to Immunomedics, Inc. common stockholders for the three-month period ended September 30, 2015 was \$15.4 million, or \$0.16 per share, as compared to a net loss of \$12.4 million, or \$0.13 per share, in the same period in 2014. The \$3.0 million increase in the net loss this 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 decreased 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 three-month period ended September 30, 2015 was \$13.3 million as compared to \$9.1 million net cash used in operating activities for the three-month period ended September 30, 2014. The increase in cash used in operating activities in fiscal 2015 primarily resulted from a \$3.0 million increase in our net loss, partially offset by non-cash expenses and movements in operating assets and liabilities.

Cash flows from investing activities. Net cash provided by investing activities for the three-months ended September 30, 2015 was \$11.6 million as compared to \$7.9 million of net cash provided by investing activities for the three months ended September 30, 2014. The increase in cash flow provided by investing activities for fiscal 2016 of \$3.7 million resulted from an increase in the sales or maturities of marketable securities, net of purchases, of \$4.1 million of marketable securities, which were partially offset by an increase in capital expenditures of \$0.4 million.

Cash flows from financing activities. Net cash provided by financing activities for the three-month period ended September 30, 2015 was \$0.1 million (a result of proceeds received from the exercise of stock options during the current year), as compared to \$0.1 million of net cash used in financing activities for the three months ended September 30, 2014.

# **Working Capital and Cash Requirements**

At September 30, 2015, we had working capital of \$76.7 million, which was approximately \$14.7 million lower than the working capital of \$91.4 million at June 30, 2015. Our cash, cash equivalents and marketable securities amounted to \$85.5 million at September 30, 2015, representing a decrease of \$14.1 million from \$99.6 million at June 30, 2015. The decreases were primarily a result of our use of \$13.3 million of cash for operations and \$0.7 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.

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 partner, Bayer. 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.

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# 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.

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# 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.

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#### 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.

A putative class action lawsuit, styled *Nasyrova v. Immunomedics, Inc.*, was filed on February 27, 2014, in the United States District Court for the District of New Jersey. The lawsuit alleged that the Company and certain of its current and former officers and directors failed to disclose and/or made material misstatements in the Company s public filings relating to the termination of the Nycomed Agreement. In particular, the complaint 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 complaint alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. On July 15, 2015, the Court granted the motion to dismiss the second amended complaint with prejudice. The Court s opinion concluded that the Company had no duty to make the disclosure of information concerning the agreement at an earlier time and that there was no misstatement or omission sufficient to support the claim. The Court ordered this action closed.

# 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

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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.

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## 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 September 30, 2015, we had an accumulated deficit of approximately \$325 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 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.

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 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

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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. 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.

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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

Limited product sales of LeukoScan<sup>®</sup>, licenses, grants and interest income from our investments.

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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. 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 September 30, 2015, we have approximately \$85.5 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 financing will be available when needed or that, if available,

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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.

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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 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.

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

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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 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.

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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 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.

# 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 sobligation 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 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

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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.

The reforms imposed by the law will significantly impact the pharmaceutical industry; however, the full effects of PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, 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.

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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

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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;

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;

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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

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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

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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 September 30, 2015, our total consolidated indebtedness was \$110.7 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.

## 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.

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

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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 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.

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

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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 September 30, 2015 we had 94,639,981 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) 4,952,737 options to purchase shares of common stock with a weighted-average exercise price of \$3.32 per share, (3) 802,918 restricted stock units to purchase shares of common stock as they are vested, (4) 9,924,256 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 22,596,748 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.

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 September 30, 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 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 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

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director s breach of the duty of care.

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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.

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.

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## 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.

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## **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.

November 4, 2015 By: /s/ Cynthia L. Sullivan

Cynthia L. Sullivan

President and Chief Executive Officer

(Principal Executive Officer)

November 4, 2015 By: /s/ Peter P. Pfreundschuh

Peter P. Pfreundschuh

Vice President, Finance and Chief Financial Officer

(Principal Financial and Accounting Officer)

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## **EXHIBIT INDEX**

Exhibit Number	Description of Document
10.1	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, incorporated by reference from Exhibit 10.1 to the Company s Current Report on Form 8-K, as filed with the Commission on July 16, 2015.
10.2	Restricted Stock Units Notice, entered into on July 14, 2015, between the Company and Dr. David M. Goldenberg., incorporated by reference from Exhibit 10.2 to the Company s Current Report on Form 8-K, as filed with the Commission on July 16, 2015.
10.3	Restricted Stock Units Agreement under the Immunomedics 2014 Long-Term Incentive Plan incorporated by reference from Exhibit 10.3 to the Company s Current Report on Form 8-K, as filed with the Commission on July 16, 2015.
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 September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language) filed electronically herewith: (i) the Condensed Consolidated Balance Sheets; (ii) 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.

<sup>\*</sup> Filed herewith.